No. 06-1498
Title: Warner-Lambert Co., LLC, et al., Petitioners
v.
Kimberly Kent, et al.
Docketed: May 14, 2007
Lower Ct: United States Court of Appeals for the Second Circuit
Case Nos.: (05-1705, 05-1743, 05-1745)
Decision Date: January 18, 2007
Rehearing Denied: February 12, 2007
Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~~~
May 10 2007	Petition for a writ of certiorari filed. (Response due June 13, 2007)
Jun 5 2007	Order extending time to file response to petition to and including July 13, 2007.
Jul 18 2007	Order further extending time to file response to petition to and including July 20, 2007.
Jul 20 2007	Brief amicus curiae of Washington Legal Foundation filed.
Jul 20 2007	Brief amicus curiae of Pharmaceutical Research and Manufacturers of America filed.
Jul 20 2007	Brief amicus curiae of Product Liability Advisory Council filed.
Jul 20 2007	Brief of respondents Kimberly Kent, et al. in opposition filed.
Jul 30 2007	Reply of petitioners Warner-Lambert Co., LLC, et al. filed. (Distributed0.
Aug 1 2007	DISTRIBUTED for Conference of September 24, 2007.
Sep 25 2007	Petition GRANTED. The brief of petitioners is to be filed with the Clerk and served upon opposing counsel on or before 2 p.m., Monday, November 5, 2007. The brief of respondents is to be filed with the Clerk and served upon opposing counsel on or before 2 p.m., Monday, December 3, 2007. A reply brief, if any, is to be filed with the Clerk and served upon opposing counsel on or before 2 p.m., Friday, December 28, 2007. Briefs of amici curiae are to be filed with the Clerk and served upon counsel for the parties on or before 2 p.m., 7 days after the brief for the party supported is filed, or if in support of neither party, within 7 days after the petitioners' brief is filed. The Chief Justice took no part in the consideration or decision of this petition.
Oct 10 2007	The time within which to file petitioners' brief on the merits is extended to and including November 21, 2007. The time within which to file respondents' brief on the merits is extended to and including January 7, 2008. A reply brief, if any, is to be filed with the Clerk and served upon opposing counsel on or before February 6, 2008. Briefs of amici curiae are to be filed with the Clerk and served upon counsel for the parties on or before 7 days after the brief for the party supported is filed, or if in support of neither party, within 7 days after the petitioners' brief is filed.
Oct 10 2007	Consent to the filing of amicus curiae briefs in support of either or neither party received from counsel for the respondents.
Nov 16 2007	Consent to the filing of amicus curiae briefs in support of either or neither party received from counsel for the petitioners.
Nov 20 2007	The time within which to file respondents' brief on the merits is further extended to and including January 11, 2008. A reply brief, if any, is to be filed with the Clerk and served upon opposing counsel on or before February 8, 2008.
Nov 21 2007	Joint appendix filed (Statement of costs received).
Nov 21 2007	Brief of petitioners Warner-Lambert Co., LLC, and Pfizer, Inc. filed.

Nov 27 2007	Brief amicus curiae of Pharmaceutical Research and Manufacturers of America filed.
Nov 27 2007	Brief amicus curiae of Product Liability Advisory Council filed.
Nov 28 2007	Brief amicus curiae of Chamber of Commerce of the United States of America filed.
Nov 28 2007	Brief amicus curiae of Generic Pharmaceutical Association filed.
Nov 28 2007	Brief amicus curiae of United States filed.
Nov 28 2007	Brief amicus curiae of Washington Legal Foundation filed.
Dec 11 2007	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Dec 21 2007	SET FOR ARGUMENT ON Monday, February 25, 2008.
Jan 11 2008	Brief amici curiae of Kansas, et al. filed.
Jan 11 2008	Brief of respondents Kimberly Kent, et al. filed.
Jan 14 2008	Motion of Kansas, et al. for leave to participate in oral argument as amici curiae and for divided argument filed.
Jan 16 2008	Letter received from the Solicitor General. (Distributed)
Jan 16 2008	CIRCULATED.
Jan 16 2008	Brief amicus curiae of American Association for Justice filed. (Distributed)
Jan 17 2008	Brief amicus curiae of Public Justice PC filed. (Distributed)
Jan 18 2008	Brief amicus curiae of AARP filed. (Distributed)
Jan 18 2008	Brief amici curiae of National Conference of State Legislatures, et al. filed. (Distributed)
Jan 22 2008	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. The Chief Justice took no part in the consideration or decision of this motion.
Jan 22 2008	Motion of Kansas, et al. for leave to participate in oral argument as amici curiae and for divided argument DENIED. The Chief Justice took no part in the consideration or decision of this motion.
Feb 8 2008	Reply of petitioners Warner-Lambert Co., LLC, et al. filed. (Distributed)
Feb 14 2008	Record received from the U.S.D.C. for the Southern District of New York. (46 boxes)
Feb 15 2008	Additional record received from the U.S.D.C. for the Southern District of New York. (5 boxes). THESE 5 BOXES ARE SEALED DOCUMENTS.
Feb 20 2008	Record received from U.S.C.A. for the 2nd Circuit. (1 box)
Feb 25 2008	Argued. For petitioners: Carter G. Phillips, Washington, D.C.; and Daryl Joseffer, Assistant to the Solicitor General, Department of Justice, Washington, D.C. (for United States, as amicus curiae.) For respondents: Allison M. Zieve, Washington, D.C.
Mar 3 2008	Adjudged to be AFFIRMED. The Chief Justice took no part in the consideration or decision of this petition.

No. ____ Supreme Court, U.S.
FILED

061498 MAY 10 2007

IN THE OFFICE OF THE CLERK

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

—v.—

KIMBERLY KENT, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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ISSUES PRESENTED FOR REVIEW

1. Whether, under the conflict preemption principles in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), federal law preempts state law to the extent that it requires the fact-finder to determine whether the defendant committed fraud on a federal agency that impacted the agency's product approval, where the agency—which is authorized by Congress to investigate and determine fraud—has not found any such fraud, and thus—as in *Buckman*—the state requirement would interfere with the agency's critical functions.

2. Whether, under the conflict preemption principles in *Buckman*, federal law preempts the provision in a Michigan statute that allows a product liability claim to be maintained against a manufacturer of an FDA-approved drug where, without an FDA finding of fraud on that agency, the fact-finder is required to make a finding under state law as to whether the manufacturer committed fraud-on-the-FDA and whether, in the absence of that fraud, the FDA would not have approved the drug.

LIST OF PARTIES TO THE PROCEEDINGS

Petitioners Warner-Lambert Company LLC and Pfizer Inc. were defendants in the district court and appellees in the court of appeals.

Respondents are the following 29 individuals who were plaintiffs in the district court and appellants in the court of appeals:

Kimberly Kent, Personal Representative of the Estate of Virginia Kent

Emmett Kent

Elizabeth M. Graham

Robert C. Graham

Connie Armstrong

Lauranane Bradley

Raymond Bradley, Sr.

Glenn Chandler

Billie Jo Flynt

Shelly Grotenhius

Judy Ann Hearn

Colleen Rose Herndon

Michael Herndon

Michael H. Kanakry

Mary Ann Kanakry

Julia Lynne Martin

Royal M. Martin

Janice L. Kimmel, Personal Representative of the Estate of Thea Martz

Mona Lorene Przytulski

David A. Rice, Personal Representative of the Estate of Robert Rice

Anita Louise Schultz

Richard P. Schultz

James Soukup, Personal Representative of the Estate of Barbara Soukup

Jennifer St. Pierre, Personal Representative of the Estate of Raymond St. Pierre

Donald R. Waun

Jean Waun

Linda Sherman

Stanley Sherman

Nancy Fisher, Individually and as Personal Representative of the Estate of Troy Fisher

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of the Court, Petitioners Warner-Lambert Company LLC and Pfizer Inc. state:

Warner-Lambert Company LLC is wholly owned by Pfizer Inc. Pfizer Inc. has no parent and no publicly held company owns more than 10% of its stock.

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Warner-Lambert Company LLC ("Warner-Lambert") and Pfizer Inc. ("Pfizer") petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit entered in this case on January 18, 2007.

OPINIONS BELOW

The court of appeals' opinion (Appendix ("App.") 1a-28a) is reported at 467 F.3d 85. The district court's order is unreported. The district court's order and the transcript in which the district court set forth its reasons supporting the order are reprinted at App. 29a-38a.

JURISDICTION

The court of appeals entered judgment on January 18, 2007. On February 12, 2007, the court of appeals denied a timely petition for rehearing. App. 39a-40a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The basis for implied conflict preemption, which is at issue here, is the Supremacy Clause of the Constitution, which provides in relevant part: "[T]he laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2, reprinted at App. 41a.

The Second Circuit opinion below conflicts with a Sixth Circuit opinion in regard to preemption of a portion of a Michigan statute that makes proof of fraud-on-the-FDA a prerequisite to a product liability action.

The relevant sections of Michigan's product liability statute provide:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller.

MICH. COMP. LAWS § 600.2946(5), reprinted at App. 42a. An exception provides for manufacturer liability, if the manufacturer

> [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5)(a), reprinted at App. 42a.

The relevant provisions of the Federal, Food, Drug, and Cosmetic Act ("FDCA") and related regulations are reprinted at App. 43a-192a and cited in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), where the Court held that state-law claims based on fraud-on-the-FDA conflict with FDCA provisions and therefore are impliedly preempted.

The pertinent statutory and regulatory provisions are as follows: FDA has a duty to ensure that "drugs are safe and effective" for their intended uses. 21 U.S.C. § 393(b)(2)(B). FDA regulates each step of the clinical

investigation process that precedes approval. *See generally* 21 U.S.C. § 355; 21 C.F.R. Parts 312, 314. A pharmaceutical company must submit a large volume of information for its "new drug application" ("NDA"). 21 U.S.C. § 355(b); 21 C.F.R. § 314.50. In reviewing clinical and scientific research to assess safety and effectiveness, "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105(c). After approval, holders of NDAs are responsible for further reporting, 21 U.S.C. § 355(k), 21 C.F.R. §§ 314.80, 314.81, which the FDA reviews to decide whether to continue approval, 21 U.S.C.§ 355(e), 21 C.F.R. § 314.150.

The federally mandated NDA process requires continual interaction between the FDA and the applicant about all aspects of the clinical trial program and the NDA. *See* 21 U.S.C. § 355; 21 C.F.R. Parts 312, 314; *see also* "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective," FDA Consumer Magazine (July-August 2002), Pub No. FDA05 3242, as revised September 2005, available at http://www.fda.gov/fdac/features/2002/402_drug.html.

FDA has the power to conduct examinations and investigations concerning prescription drugs, 21 U.S.C. § 372, and the United States may enforce FDA's mandate by seeking injunctive relief, seizure of misbranded drugs, or criminal and civil penalties. 21 U.S.C. §§ 332-334.

FDA is empowered to investigate and punish fraud under 21 U.S.C. § 372. Citizens may report wrongdoing to the FDA and petition the agency to take action under 21 C.F.R. § 10.30. The FDA may pursue a wrongdoer under criminal statutes that proscribe false statements to

the federal government. *Buckman*, 531 U.S. at 349 (citing 18 U.S.C. § 1001). The agency also has authority to address fraud by seeking injunctive relief and civil penalties. 21 U.S.C. §§ 332, 333; *see also* 21 U.S.C. § 355(e)(5) (allowing FDA to withdraw drug approval where application contains any untrue statement of a material fact). FDA has established an enforcement policy concerning fraud in pre-market submissions that sets forth the remedies it may pursue. *See* Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46,191, 46,199-200 (Sept. 10, 1991); *see also* FDA Compliance Policy Guide § 120.100, "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," issued July 1, 1991 (announced in 55 Fed. Reg. 52,323 (Dec. 21, 1990)), available at http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg120-100.html. All lawsuits to enforce the FDCA's provisions "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

STATEMENT OF THE CASE

The basis for federal jurisdiction in the district court is diversity. 28 U.S.C. § 1332. Respondents (hereinafter "Plaintiffs") are Michigan citizens, who are plaintiffs in product liability actions filed in Michigan state court against Petitioners Warner-Lambert and Pfizer (collectively "Warner-Lambert")[1], claiming injuries from a prescription drug, Rezulin, approved by FDA for treatment of diabetes. Warner-Lambert removed those actions to federal district court in Michigan. The Judicial Panel on Multidistrict Litigation established the Rezulin Multidistrict Litigation ("Rezulin MDL") pursuant to

[1] Warner-Lambert manufactured Rezulin while it was marketed from March 1997 to March 2000. Pfizer acquired Warner-Lambert in June 2000.

28 U.S.C. § 1407, and transferred these cases and others to the Rezulin MDL court in the Southern District of New York.[2]

In their state law product liability claims under the Michigan statute quoted above, several of the Plaintiffs allege that Warner-Lambert

> "knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market." App. 337a, 344a, 354a.

The FDA approved Rezulin as safe and effective for use consistent with its labeling at all times while it was marketed. After FDA approved Rezulin for sale in March 1997, the FDA continually scrutinized the drug and its warning labels and maintained its approval status at all times until Warner-Lambert withdrew Rezulin in March 2000. Warner-Lambert withdrew the drug at FDA's suggestion because of adverse side effects and the advent of two new similar drugs in the same class that rendered Rezulin outmoded.[3] A number of physicians

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[2] The five cases at issue in this appeal were transferred to the Rezulin MDL. *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-1 (J.P.M.L. June 21, 2000) (*Kent*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-7 (J.P.M.L. Dec. 12, 2000) (*Graham*). *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-34 (J.P.M.L. October 11, 2001) (*Armstrong*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-56 (J.P.M.L. April 23, 2003) (*Sherman*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-69 (J.P.M.L. Apr. 23, 2004) (*Fisher*).

[3] *See* App. 7a; Center for Drug Evaluation and Research, Food and Drug Administration, Endocrinologic and Metabolic Drugs Advisory Committee Meeting Transcript ("EMDAC") at 82 (May 19, 2000), available at http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3615t1.pdf.

and patients sought to keep the drug on the market because of its therapeutic benefits in treating diabetes.[4]

Warner-Lambert moved for judgment on the pleadings on the ground that Plaintiffs could not establish, under the Michigan product liability statute, that Rezulin—as an FDA-approved drug—was "defective." Warner-Lambert further argued that a portion of the Michigan statute—which required plaintiffs to obtain a state law finding that Warner-Lambert had engaged in fraud-on-the-FDA without which the FDA would not have approved Rezulin—was impliedly preempted under *Buckman*. The motion relied on *Buckman's* holding that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. The motion also relied on *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), which applied *Buckman* to preempt the portion of the Michigan statute requiring a state law finding of fraud-on-the-FDA (where the FDA had not itself found fraud). *Garcia* also held that the remainder of the statute, which provided that FDA-approved drugs are not *defective* for purposes of Michigan products liability law, should be severed and enforced independently.

The district court granted Warner-Lambert's motion for judgment on the pleadings, relying on *Garcia* and its application of *Buckman*. App. 29a-38a. The district court reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again," resulting in "enormous" "interference with the proper discharge of

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[4] EMDAC, n. 3, *supra*, at 13-14, 17-27.

the mission that Congress created the FDA to perform." App. 35a-36a.

In direct conflict with *Garcia*, the Second Circuit reversed the district court decision. App. 1a-28a. The court relied on a presumption against preemption, citing *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996), even though *Buckman* had explicitly rejected that presumption for state law claims of fraud-on-the-FDA. The Second Circuit read *Buckman* narrowly so that it applied only to claims based "solely" on fraud-on-the-FDA, which in its view did not include claims requiring plaintiffs to prove the exception in the Michigan statute. The court of appeals also was dismissive of *Buckman's* concerns with the adverse impact that state law determinations of fraud-on-the-FDA could have on the FDA's internal operations and the regulatory process.

REASONS FOR GRANTING THE PETITION

The Second Circuit decision threatens to upset the basic understanding of preemption law that has informed this Court's decisions since *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), cited in *Buckman*, 531 U.S. at 347. As *Buckman* held, under this line of decisions there is no presumption against preemption of state law with respect to an issue that is not historically within a field occupied by the states, such as finding fraud on a federal agency that affected the agency's decision-making. *Id.* at 348. *Buckman* found that the FDA approval process was a "comprehensive scheme." The Court concluded that "[s]tate law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and would "cause applicants to fear that their disclosures to the FDA, although deemed

appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 348, 350, 351.

The circuit courts are sharply split in their application of *Buckman* and the preemption doctrine. The Second Circuit here confined *Buckman* to the narrow circumstance where a plaintiff has asserted a stand-alone cause of action for "fraud-on-the-FDA"—in essence a claim that is pleaded entirely on that theory. App. 19a-23a. A number of district courts as well as a state court have adopted a similarly narrow approach. *See, e.g., Ackermann v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 WL 354492, at *8 (E.D. Tex. Dec. 7, 2006); *In re: St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396, 2004 WL 45503, at *13 (D. Minn. Jan. 5, 2004); *Bryant v. Hoffman-LaRoche, Inc.*, 585 S.E.2d 723, 725 (Ga. Ct. App. 2003).[5]

The Sixth Circuit and Ninth Circuits, as well as the Third Circuit prior to *Buckman*, have taken a more functional approach—applying *Buckman* to preempt state law to the extent that it requires a plaintiff to establish a fraud on a federal agency, regardless of the technical nature of the pleading in which that requirement arises. This line of cases has looked to whether the state-law requirement—that the fact-finder make a determination as to whether a federal agency has been defrauded—would lead to the same impositions on the federal agency that concerned this Court in *Buckman*. As shown above, the Sixth Circuit's preemption decision in *Garcia* squarely conflicts with the Second Circuit decision here on this issue. Taking an approach like that of the Sixth Circuit, the Ninth Circuit has held that under "[t]he rationale articulated by the Supreme Court in *Buckman*,"

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[5] All unpublished decisions cited herein are reprinted at App. 193a-331a.

plaintiff's claim for tortious interference with prospective business advantage was preempted where plaintiff would have to prove that defendant committed a fraud on the Environmental Protection Agency to prevail. *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1205-06 (9th Cir. 2001). The Third Circuit, in a decision that presaged *Buckman*, held that "[i]f a medical device manufacturer's claim that the MDA pre-empts a plaintiff's cause of action depends in the first instance upon proof that its Premarket Approval was not fraudulently obtained, courts would have to engage in the intrusive inquiry which we have demonstrated is forbidden." *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995).

Federal district courts and state courts have rendered holdings consistent with the Sixth, Ninth and Third Circuits' approach, and contrary to the Second Circuit's narrow view of *Buckman*. *See Webster v. Pacesetter*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (plaintiffs precluded by *Buckman* from "arguing" that defendants failed to comply with FDA regulations in regard to design and labeling of medical device, where their claim was denominated as for common law failure to warn); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 851 (W.D. Tex. 2001) (dismissed unclean hands defense to trademark infringement suit premised on alleged misbranding under the FDCA on ground that, citing *Buckman*, the defense as pleaded would have "require[d] interpretation and application of FDA regulations," which was better left to FDA to determine); *Baker v. St. Jude Medical, S.C., Inc.*, 178 S.W.3d 127, 138 (Tex. Ct. App. 2005) (common law fraud claims preempted where plaintiffs alleged that "St. Jude withheld, or unreasonably delayed, in providing the FDA with information that it had regarding adverse effects associated with Silzone heart valve"); *Ledbetter v. Merck & Co., Inc.*, No.

2005-59499, slip op. at 8 (Tex. Dist. Ct. Harris County Apr. 20, 2007) (held that federal law preempted portion of state statute that required that "in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA," and concluded that "[w]hether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same").

The issue presented in this case is a specific manifestation of the split in the circuits and lower courts described above—whether federal law preempts the portion of a state statute that requires a fact-finder to make a determination concerning alleged fraud-on-the-FDA, absent a determination by the FDA on that issue. In *Garcia,* the Sixth Circuit had held that implied conflict preemption applied to the portion of the Michigan statute that authorized finders of fact to decide under state law—as a prerequisite to product liability claims—whether there was material fraud-on-the-FDA, unless the FDA itself had made such a finding. *Garcia* recognized that the powerful concerns expressed in *Buckman* were sparked by the intrusion of such a state law requirement on the FDA's regulatory process. Moreover, the Sixth Circuit held that those concerns are equally relevant whether they are raised in a state common law action for fraud-on-the-FDA or under a statutory exception to a provision that treats FDA drug approval as dispositive of product liability claims.

The Second Circuit took precisely the opposite position when it exalted form over substance to rule that the concerns expressed in *Buckman* somehow vanish because of the difference in the procedural posture in which a court under state law would be required to determine if there was material fraud-on-the-FDA. As a result, the Second Circuit adopted an unduly narrow reading of *Buckman* as

applying only to stand-alone claims that are in effect denominated as for fraud-on-the-FDA. In so ruling, the Second Circuit misread *Medtronic* and jettisoned a half century of preemption law culminating with *Buckman*. Indeed, the decision of the Second Circuit below is the most limited interpretation of *Buckman* to date and most egregiously ignores *Buckman*'s rationale.

Moreover, the Second Circuit's holding will interfere with the FDA's ability to perform its critical functions, which is precisely what this Court sought to avoid in *Buckman*. 531 U.S. at 349-51. Findings of fraud-on-the-FDA would inevitably disrupt the regulatory process by encouraging manufacturers to supply unnecessary information to the FDA for fear that the failure to do so will lead to state-law liability; by discouraging manufacturers from seeking approval for beneficial drugs that are not risk-free; by distorting the FDA's decision-making process to anticipate potential state-law review of that process; and by burdening FDA personnel who are ordered to testify as witnesses in state-law products liability cases concerning the FDA's decision-making process.

An additional reason for granting certiorari in this case is that the issues reach beyond the Michigan statute on which the Sixth and Second Circuit are in conflict. As part of tort reform efforts throughout the country, other states have enacted statutes limiting claims or damage recoveries for FDA-approved drugs unless the finder of fact determines under state law that there was fraud-on-the-FDA. Thus, Texas has enacted legislation, which—similar to the Michigan statute—provides for a presumption that FDA-approved warnings on pharmaceutical products are adequate, which can be rebutted if the plaintiff establishes fraud-on-the-FDA. *See* TEX. CIV. PRAC. & REM. CODE § 82.007. In addition, six states have a fraud-on-the-FDA exception to a rule bar-

ring punitive damages for FDA-approved drugs. *See* ARIZ. REV. STAT. § 12-701; N.J. STAT. ANN. § 2A:58C-5(c); N.D. CENT. CODE § 32-03.2-11(6), (7)(a); OHIO REV. CODE ANN. § 2307.80(C); OR. REV. STAT. ANN. § 30.927; UTAH CODE ANN. § 78-18-2. All of these statutes reflect a trend to limit state law product liability claims or recoveries where products have been approved and are regulated by the federal government.[6] Thus, the issue raised by this petition has a broad impact on other statutes. A Michigan appellate court, a Texas state court and federal district courts in Tennessee, Pennsylvania and Arizona have followed the Sixth Circuit decision in finding preemption of such state law requirements, while a district court in Texas adopted the formalistic approach of the Second Circuit here.[7] *See* discussion of *Garcia* in Point I, *infra*.

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[6] David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 20 22 (2005).

[7] *See Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006) (agreeing with the Sixth Circuit's decision in *Garcia* that the fraud on the FDA exception in MICH. COMP. LAWS § 600.2946(5)(a) is partially preempted by federal law); *Ledbetter v. Merck & Co., Inc.*, No. 2005-59499, slip op. at 9 (Tex. Dist. Ct. Harris County Apr. 20, 2007) (following *Garcia* and holding that the fraud on the FDA exception under Tex. Civ. Prac. & Rem. Code § 82.007 is preempted except where FDA has "made a determination that material and relevant information was either withheld or misrepresented concerning Vioxx"). *In re Aredia and Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266, *8, *9 n.17 (M.D. Tenn. Feb. 27, 2007) (New Jersey statute that "immunizes drug manufacturers from punitive damage liability *unless* the plaintiff can prove fraud on the FDA" is impliedly preempted unless the FDA itself finds fraud) (emphasis in original); *Henderson v. Merck & Co., Inc.*, No. 04-CV-05987-LDD, 2005 WL 2600220, *11 (E.D. Pa. Oct. 11, 2005) (following the "holdings of *Buckman* and *Garcia* and find[ing] that [the exceptions for fraud-on-the-FDA in the Michigan statute] are preempted by the FDCA in most situations"); *Kobar v. Novartis Corporation*, 378 F. Supp. 2d 1166, 1173 (D. Ariz. 2005) (both fraud on

State legislatures need direction from this Court on how they should conform their existing statutes or new legislation to federal preemption standards. The lower courts likewise need instruction on these preemption issues as they relate to the overlap between *Buckman* and *Medtronic*. Only this Court can provide the necessary guidance in this important area of federal constitutional law.

I. THE SECOND CIRCUIT'S DECISION BELOW IS IN CONFLICT WITH THE SIXTH CIRCUIT, AND WITH THE RATIONALE OF THIS COURT IN *BUCKMAN*, AS WELL AS THE THIRD AND NINTH CIRCUITS IN ANALAGOUS CASES, AS TO WHEN A STATE LAW REQUIREMENT OF A FINDING OF FRAUD ON A FEDERAL AGENCY IS IMPLIEDLY PREEMPTED.

Buckman—In *Buckman*, this Court held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. *Buckman* is one of a series of decisions in which the Court has charted a course between federal preemption and proper state authority. Thus, *Buckman* began its analysis by explaining that "[p]olicing fraud against federal agencies is hardly 'a field which the states have traditionally occupied . . . .' " *Id.* at 348 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In *Rice*, the Court applied an "assumption" against superseding state powers because states had for

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the-FDA claim and statute requiring plaintiff to prove fraud to avoid punitive damages "place state courts, as finders of fact," in the position of deciding what role the withheld information would have had in the "FDA's complicated approval process."). *But see Ackermann v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 WL 354492, at *8 (E.D. Tex. Dec. 7, 2006) (plaintiff's evidence of fraud on the-FDA rebuts presumption of no liability and does not in itself establish liability).

years regulated warehouses while the federal government had only recently decided to regulate them under a new statute. *Rice*, 331 U.S. at 330. The Court there found that comprehensive federal regulation overcame the "assumption." *Id.* at 236. In contrast, where the interests at stake are "uniquely federal" in nature, the conflict with the state need not be "as sharp" because of a concern that "the application of state law would 'frustrate specific objectives' of federal legislation." *Boyle v. United Technologies Corp.*, 487 U.S. 500, 504, 507 (1988) (finding preemption of common law design defect claim involving military equipment where federal law only authorized such a claim on a limited basis), cited in *Buckman*, 531 U.S. at 347.

Applying these well-established principles, this Court in *Buckman* explained that no presumption against preemption applies where "the relationship between a federal agency and the entity it regulates is inherently federal in character . . . ." 531 U.S. at 347. As the Court further explained, permitting fraud-on-the-FDA determinations under state law would frustrate the "flexibility [that] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. In addition, it would "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives." *Id.* at 350. Furthermore, allowing fraud-on-the-FDA claims would "dramatically increase the burdens facing potential applicants" in a manner "not contemplated by Congress," and create an "incentive" for manufacturers "to submit a deluge of information that the [FDA] neither wants nor needs" for "fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court." *Id.* at 350-51.

The same rationale precludes application of the Michigan statute (and similar state statutes) to the extent that those statutes require plaintiffs to prove fraud-on-the-FDA as a condition of recovery under state law. As with the Medical Device Amendments to the FDCA at issue in *Buckman*, the FDCA "sets forth a comprehensive scheme" for determining if an applicant is entitled to new drug approval. *Buckman*, 531 U.S. at 348. Therefore, as in *Buckman*, petitioner's dealings with FDA and the "very subject matter of petitioner's statements" to FDA were "dictated by that statute's provisions," and the relationship between petitioner and the FDA is inherently federal in character. *Id.* at 347-48. Thus, as in *Buckman*, no presumption against preemption applies.

Moreover, the FDCA, regulatory and other statutory provisions—described in *Buckman* as "aimed at detecting, deterring, and punishing false statements" during the approval process—are equally relevant here. *Id.* at 349. As described in *Buckman*, "citizens may report wrongdoing and petition the agency to take action." *Id.* (citing 21 C.F.R. § 10.30). The FDA and the federal government make extensive use of the provisions cited in *Buckman*, 531 U.S. at 349, to investigate and sanction fraud-on-the-FDA.[8] In the interactive drug regulatory

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[8] *See e.g., U.S. v. Barile*, 286 F.3d 749 (4th Cir. 2002) (criminal prosecution for false statements to FDA); *U.S. v. Prigmore*, 243 F.3d 1 (1st Cir. 2001) (prosecution for conspiring to defraud FDA); *U.S. v. Leichter*, 96 F. Supp. 2d 5 (D. Mass. 2000) (conspiracy to defraud FDA); FDA News P03 92, *Louisiana Ophthalmologist Fined $1.1 Million by FDA For Clinical Study Violations* (Nov. 5, 2003), available at http://www.fda.gov/bbs/topics/NEWS/2003/NEW00972.html; Michelle Meadows, *Company Gets a Guilty Reading in Glucose Monitor Case*, FDA CONSUMER MAGAZINE (March April 2001), available at http://www.fda.gov/fdac/departs/2001/201_irs.html (pharmaceutical manufacturer pleaded guilty to misdemeanor charges and agreed to pay $60 million in criminal and civil fines for *inter alia*, filing false or misleading information).

process, as in *Buckman*, "flexibility" is a "critical component of the framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. Superimposing state law determinations of any sort on top of "the FDA's detailed regulatory regime. . . will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA . . . ." *Id.* at 350. Such burdens could discourage applicants from filing for approval of beneficial drugs that are not risk-free, and cause applicants to submit a deluge of information not wanted by FDA to assure that their submissions will not "later be judged insufficient in state court." *Id.* at 351. Plainly, these concerns arise under any state law that makes a finding of fraud-on-the-FDA a prerequisite to establishing liability under the state's tort law, when the FDA is empowered to make its own potentially inconsistent findings in regard to any such alleged fraud. Whether the requirement of a finding of fraud-on-the-FDA is called an "element" of the state-law claim or a "threshold prerequisite" is irrelevant to the vital institutional concerns expressed in *Buckman*.

The concurring opinion in *Buckman* suggested, as an accommodation between state and federal interests, that the conflict between the FDCA regulatory scheme and state tort fraud actions vanishes if the FDA has exercised its statutory power to find that fraud by an applicant induced it to approve a drug. As Justice Stevens stated, if "the FDA had determined that petitioner had committed fraud," plaintiffs' "state law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions," and would not lead to "second-guessing the FDA's decision making or overburdening its personnel." 531 U.S. at 354. Once the FDA decides that there has been fraud, the burdens on the

administrative process and perverse incentives to drug applicants no longer pertain. This same accommodation was adopted by *Garcia* and ignored by the Second Circuit. It is as valid for the Michigan statutory exception's requirement as it was for the common law fraud-on-the-FDA claims in *Buckman*. In both procedural settings, "an essential link in the chain of causation that respondent must prove in order to prevail is that, but for petitioner's fraud, the allegedly defective [medical product] would not have reached the market." 531 U.S. at 353.

The Sixth Circuit decision in Garcia—Garcia applied *Buckman* to find partial preemption of what in reality is a statutory fraud-on-the-FDA claim, stemming from the exception in the Michigan statute that allows a product liability claim only where the fact-finder concludes that the defendant made intentional misrepresentations to FDA without which FDA would not have approved the medication. 385 F.3d 961. The "Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA rather than a specific cause of action for fraud on the FDA. This difference, however, is immaterial in light of *Buckman*." *Id.* at 965-66 (footnote omitted). In both instances, "a plaintiff asks a state court to find bribery or fraud on the FDA." *Id.* at 967. Under the statute, a plaintiff must establish the exceptions to the immunity in the statute for FDA approved drugs "on the basis of *state court* findings of fraud on the FDA." *Id.* at 966 (emphasis in original). The Sixth Circuit concluded: "Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* at 966. For Plaintiff's here, as in *Buckman*, "the existence of these federal enactments is a critical element in their case." 531 U.S. at 353. Accordingly, *Buckman's* conclusion is fully applicable in the circumstances here, *i.e.*, that "this sort

of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme." *Id.*

The Sixth Circuit was careful to avoid reading *Buckman* too broadly, for it recognized that "the same concerns do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process" and, therefore, in that circumstance, the Michigan statutory exception is not impliedly preempted. *Garcia*, 385 F.3d at 966 (emphasis in original). At bottom, the FDA is the appropriate forum for deciding, through its mandated procedures, whether it was deceived by a fraud by the applicant. Because a potential plaintiff may seek an FDA finding of fraud that has materially affected its decision-making, the partial preemption found by the Sixth Circuit does no more than recognize the FDA's primary jurisdiction over a claim of fraud on the agency. *See* 21 C.F.R. § 10.25(b) ("FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate . . . .").

Plaintiffs in *Garcia* had offered no proof of fraud. They did not seek to satisfy the statutory exception but rather to use *Buckman* to persuade the court to overturn the entire immunity provision including the exception. Instead, the Sixth Circuit held that under Michigan law, while the exception was partially preempted, the statutory immunity for FDA-approved drugs should be preserved. *Garcia*, 385 F.3d at 967. As the court explained, "the Michigan legislature would have preferred the situation where drug manufacturers would enjoy immunity in the absence of a federal finding of . . . fraud on the FDA" to "the situation urged by the Plaintiff where drug manufacturers would enjoy no immunity at all." *Id.* The court of appeals relied on the Michigan severance provisions to support this holding. *Id.* at 966-67. Because

the State of Michigan is in the Sixth Circuit, that court's interpretation of the Michigan statute is entitled to deference. Its decision to find partial preemption is a federal question that was correctly decided under *Buckman*.[9]

A Michigan appellate court adopted *Garcia's* "holding that the fraud on the FDA exception is preempted by federal law unless the FDA itself determines that it was defrauded," and also agreed with its Michigan law holding regarding severance of the preempted portion of the statute. *Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006). *Accord, Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760 (E.D. Mich. 2006).

The recurring nature of the issue presented by the conflict between *Garcia* and the Second Circuit is illustrated by the decisions cited in note 7, *supra*, addressing preemption of analogous state statutes, which followed the Sixth Circuit, and another that adopted the narrow view of the Second Circuit in finding no preemption of an analogous provision in a Texas statute.

The Second Circuit's Decision Below—The Second Circuit essentially rejected this Court's rationale in *Buckman* at every step of its opinion. App. 1a-28a.

First, the Second Circuit applied a presumption against federal preemption because the "Michigan legislature's desire to rein in state-based tort liability falls squarely within the prerogative to 'regulat[e] matters of public health and safety . . . .' " App. 19a. This argument flies in the face of *Buckman* and this Court's preemption case law discussed in that opinion, which hold that there is no presumption against preemption when

[9] The Sixth Circuit's interpretation of Michigan law is controlling in other circuits. *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir.1981), cited by the court of appeals below at App. 11a.

the state legislates regarding "the relationship between a federal agency and the entity it regulates," which relationship is "inherently federal in character." *Buckman*, 531 U.S. at 347. This case is sharply distinguishable from the state law claims in *Medtronic*, on which the Second Circuit relied (App. at 21a-22a), all of which predated the federal regulatory enactments, and did not interfere in any way with regulatory oversight over fraud investigations and enforcement.

Moreover, the Second Circuit's analysis is flawed because it treats Michigan's purpose as decisive, whereas *Buckman* focuses on the conflict with federal regulatory authority in an inherently federal area, without regard to the state's purpose. In addition, the Second Circuit's assertion fails to acknowledge that *Garcia* allows the state to "rein in" tort liability *and* to have an exception for fraud-on-the-FDA where the FDA has found fraud on the agency. The Sixth Circuit limited its preemption holding to cases where the fact-finder in a state-law action is required to find fraud-on-the-FDA as a condition to liability. That results in a state intrusion into "policing" fraud against a federal agency because, according to *Buckman*, the FDA has exclusive authority to decide whether there was a fraud on the agency and what consequences should follow.

The court below latched onto *Buckman*'s reference to the state law claim there being "solely" based on defrauding the FDA. But under the Michigan statute, product liability claims can succeed *only* if there is fraud-on-the-FDA—without which FDA would not have approved or would have withdrawn approval of the drug—*and* the product is proved defective. It is not sensible to suggest that by imposing the very same requirement of fraud-on-the-FDA and adding another requirement, a state law interferes with the FDA's regulatory policies any less than does

a statute requiring only fraud-on-the-FDA. The consequences to the federal regulatory process of a dual state/federal regime for finding fraud, and whether the fraud impacted regulatory approval, make this a difference without a distinction. *Buckman's* preemption rationale applies to all state law litigation of fraud-on-the-FDA, whether by statute or by a common law fraud claim.

Next, the court below purported to distinguish *Buckman* on the ground that plaintiffs here did not assert "fraud-on-the-FDA" claims. App. 19a-23a. However, preemption in *Buckman* did not turn on the *name* given to the state law requirement, but on the requirement itself and its intrusion into the FDA's exclusive authority over whether an applicant committed fraud against the agency. Furthermore, the court below wrongly concluded that the Sixth Circuit had "gutted" plaintiffs' traditional state law claims. App. 20a. The Michigan legislature—not the Sixth Circuit—altered the state's product liability regime.

The narrow procedural focus of the Second Circuit below is evident in its statement that under the Michigan statute, "FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature . . . ." App. 23a (emphasis in original). This statement is off the mark for two reasons. First, *Garcia* held—under Michigan law—that to invoke the exception, "*plaintiff* asks a court to find bribery or fraud on the FDA," 385 F. 3d 966 (emphasis added). The Michigan Supreme Court has characterized the fraud-on-the-FDA statutory exception as a "claim" that plaintiff must "make." *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003). Secondly, all of the concerns in *Buckman* remain whether FDA approval is raised as part of a plaintiff's prima facie case—as is

implicit in Plaintiffs' allegations here that fraud-on-the-FDA led to its approval of Rezulin—or, as a defense.

Moreover, where, as here, Plaintiffs alleged fraud-on-the-FDA in order to satisfy the statute's requirement, it follows that such fraud is an element of their state law claims. Furthermore, because the statutory requirement to prove fraud-on-the-FDA arises whenever there is an FDA-approved drug, which is a matter of public record and indisputable, it is immaterial whether that requirement is characterized as part of plaintiff's claim or as a rebuttal to a defense.

If a state created its own administrative agency to monitor and sanction fraud-on-the-FDA, the conflict between the state system and the federal interest would be unquestioned. *Buckman* held that this conflict is not lessened because the state seeks to regulate fraud through private litigation. Indeed, judicial intervention in the FDA regulatory process is likely to be even more intrusive as different state courts and juries potentially make different findings on what is required in the federal regulatory process, on when applicants have not satisfied those requirements, and on whether any omissions would have caused the federal agency to deny approval.

Finally, the Second Circuit brushed aside *Buckman*'s emphasis on "practical concerns" that would adversely impact the regulatory process, because—according to the Second Circuit—the same concerns purportedly would arise if a state court or jury were allowed to consider evidence of fraud-on-the-FDA. App. 24a. That possibility was as true in *Buckman* as it is here. To avoid disastrous effects on the regulatory process, *Buckman* has been properly applied so that evidence in the trial of common law or statutory claims "will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed

from the FDA." *Bouchard v. American Home Products Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002). Moreover, the exception in the Michigan statute goes beyond allowing evidence of fraud-on-the-FDA, and in addition permits state law findings of fraud and materiality, which can be inconsistent with the FDA's position.

II. THE CIRCUIT SPLIT WILL LEAD TO CONSEQUENCES TO THE FEDERAL REGULATORY SCHEME, WHICH *BUCKMAN* SOUGHT TO AVOID.

By opening the door to inevitable inconsistencies between state and FDA determinations of fraud on the agency, the Second Circuit's decision will have a negative impact on the FDA's drug review process and its administration of the FDCA, which in turn will interfere with the FDA's mission to protect public health. *See Buckman*, 531 U.S. at 350. The FDA has "complete discretion" in addressing possible statutory or regulatory violations. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Under the Second Circuit's decision, state law findings of fraud-on-the-FDA might conflict not only with those of other states, but also with FDA's own determinations. For example, if the FDA denied a Citizen Petition asking the agency to find that an applicant committed fraud-on-the-FDA, a state court or jury could—under the Michigan statute—second guess FDA's finding. If FDA found no fraud, any state law decision that found fraud, pursuant to statute or at common law, would undermine public confidence in the FDA, thereby creating havoc in the regulatory process. *See Garner v. Teamsters*, 346 U.S. 485, 490-91 (1953) ("multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law").

Moreover, allowing state law determinations of fraud-on-the-FDA would distort the behavior of regulated entities, which up to now could base their interactions with the agency on federal requirements alone rather than those of numerous state courts. Under the FDCA and FDA regulations, the applicant must closely cooperate with FDA to determine how clinical trials are to be run and what data must be submitted. Superimposing a state law regime based on litigation in civil court actions will grind that interactive process to a halt if—at each of the many steps in the process—companies must consider not merely what FDA asks but what the states might have wanted the FDA to have. Moreover, state law determinations of fraud-on-the-FDA could distort the FDA's internal decision-making by tempting it to anticipate and respond to state court decisions. The FDA's control over clinical trials and related approval requirements is sufficiently complex today, that no additional expense, delay or confusion is warranted from state sources. *See Buckman*, 531 U.S. at 351. Indeed, the cost of research and development of a new drug, including the FDA approval process, has been estimated at $802 million.[10]

Furthermore, as the district court recognized in its opinion below, the Michigan statute threatens to embroil FDA in state court litigation. App. 35a-36a. Litigants naturally will seek out the best evidence of whether an agency has been defrauded and the impact of that fraud on approval. Plaintiffs and defendants will seek discovery on whether there was fraud and whether absent the fraud, the FDA would have withheld approval of the drug, or would have withdrawn its approval. This will necessitate combing through thousands of pages of NDA

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[10] Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 JOURNAL OF HEALTH ECONOMICS 151, 166 (2003).

material, followed by burdensome questioning of FDA personnel. Intrusive discovery into federal agency officials' states of mind, and the courses of action that agency officials might have taken under hypothetical scenarios long after the fact, would divert FDA resources from the central purpose assigned by Congress.

Nor would FDA personnel necessarily be shielded from testifying. FDA can decline to permit its employees to testify about their official duties, pursuant to 21 C.F.R. § 20.1. But courts do not always honor FDA's decisions in this regard. *See, e.g., In re Vioxx Prods. Liab. Litig.* 235 F.R.D. 334 (E.D. La. 2006) (denying FDA motion to quash deposition subpoena for FDA official). Moreover, if agency officials do not testify, juries would then be free to speculate on the key issues of fraud and what the agency might have done absent the fraud, which might conflict with the FDA's own judgment.

Notably, the Second Circuit ruling is at odds not just with a sister circuit, but with the circuit having the most direct responsibility for hearing claims arising under Michigan statutory law. The conflict in circuits should be resolved so that Michigan residents are not encouraged to sue in a distant forum within the Second Circuit, which they could do—given nationwide jurisdiction over pharmaceutical manufacturers—to nullify the sound decision of the Sixth Circuit. The conflict also will inject forum shopping considerations into the MDL process, which today handles much of the pharmaceutical product liability litigation.

This Court should clarify the law for state legislatures, state courts and lower federal courts by granting this petition and ruling that federal law preempts any state law to the extent it requires a fact-finder, in the absence of a fraud finding by the FDA, to determine under state

law whether a pharmaceutical manufacturer has committed a fraud-on-the-FDA that resulted in approval of a prescription drug. The disruption of the FDA administrative and regulatory process that *Buckman* sought to avoid will reappear if this conflict is not resolved by a sensible and functional application of this Court's preemption pronouncements.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: May 10, 2007

APPENDIX

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UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2005

(Argued: November 8, 2005

Decided: October 5, 2006

Amended: January 18, 2007)

Docket Nos. 05-1705-cv(L), 05-1743-cv(CON), 05-1745-cv(CON)

CAESAR DESIANO ET AL.,

Plaintiffs-Appellants,

—v.—

WARNER–LAMBERT & CO., ET AL,

Defendants-Appellees.

Before:

FEINBERG, CALABRESI, and B.D. PARKER,

Circuit Judges.

Appeal from grant of judgment on the pleadings in favor of Defendants-Appellees. The United States District Court for the Southern District of New York (Kaplan, J.) held that Michigan law shields pharmaceutical companies from products liability claims unless

there is, *inter alia*, evidence that the drug company misrepresented or withheld material information in obtaining FDA approval for its drug. The court concluded that Michigan plaintiffs' claims could not be distinguished from the "fraud-on-the-FDA" claim found to be preempted by federal law in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). We disagree. A presumption against federal preemption of state law applies in the context of traditional common law claims preserved by states to protect the health and safety of their citizens. Moreover, a fraud-based exception to Michigan's immunity statute does not raise the same concerns that animated the Supreme Court's decision in *Buckman*. Vacated and remanded.

DAVID B. RODES, Goldberg, Persky & White, P.C., Pittsburg, PA (Vincent J. Carter, Girardi Keese, Los Angeles, CA; David R. Parker, Charfoos & Christensen, PC, Detroit, MI; Jerome D. Goldberg, Varjabedian Attorneys, Southfield, MI, *on the brief*), *for Plaintiffs-Appellants*.

DAVID KLINGSBERG, Kaye Scholer LLP (Wendy S. Dowse, *on the brief*), New York, NY, *for Defendants-Respondents*.

CALABRESI, *Circuit Judge*:

It has long fallen within the province of states to safeguard the health and safety of their citizens. *See Medtronic v. Lohr*, 518 U.S. 470, 475 (1996). Consonant with the "historic primacy of state regulation" of

these matters, *see Medtronic*, 518 U.S. at 485, the power of states to govern in this field is considerable and undisputed. *See Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" (quoting *Slaughter-House Cases*, 16 Wall. 36, 62, 21 L.Ed. 394 (1873); *Thorpe v. Rutland & Burlington R. Co.*, 27 Vt. 140, 149 (1855)). Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as "a critical component of the States' traditional ability to protect the health and safety of their citizens." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (1992) (Blackmun, J., concurring in part and dissenting in part). In recent years, some states, in exercising their traditional authority with respect to the pharmaceutical industry, have narrowed common law liability in order to insulate drug companies from burdensome litigation. *See generally* David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 22-23 (2005). The case before us concerns a supposed conflict between federal law and the products liability regime of one such state.

In 1995, the State of Michigan enacted legislation immunizing drugmakers from products liability claims so long as the Food and Drug Administration ("FDA") approved the pharmaceutical product at issue. *See* Mich. Comp. Laws § 600.2946(5) (hereinafter "M.C.L. § 2946(5)"). Michigan's immunity scheme contains an exception that preserves liability if the pharmaceutical company withheld or misrepresented information that would have altered the FDA's decision to approve the drug. In 2001, in a case dealing with different legal

rules and a different jurisdiction, the Supreme Court held that state "fraud-on-the-FDA" claims were impliedly preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). The question presented by this appeal is whether, under the rationale of *Buckman*, federal law also preempts traditional common law claims that survive a state's legislative narrowing of common law liability through a fraud exception to that statutory limitation. For the reasons below, we conclude that federal law does not preempt these state claims. We therefore vacate the District Court's grant of judgment on the pleadings and remand the case for further proceedings consistent with this opinion.

BACKGROUND

A. Michigan's Immunity Statute

Prior to its amendment in 1995, Michigan's products liability statute provided that "evidence showing compliance with governmental or industry standards was admissible in a products liability action in determining if the standard of care had been met." *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 130 (Mich. 2003). In describing the pre-amendment law, the Supreme Court of Michigan emphasized the limits on the probative value of this sort of evidence of compliance:

> We note that our Legislature has recently enacted a statute which provides that industrial and governmental standards are admissible in products liability actions [citing earlier version of M.C.L. § 600.2946]. The statute does not provide that such standards are con-

> clusive. [We affirm the position] that compliance with governmental and industrial standards is admissible as evidence but is not conclusive as to whether the defendant was negligent or the product was defective.

Owens v. Allis-Chalmers Corp., 326 N.W.2d 372, 375-76 (Mich. 1982).

In 1995, Michigan's legislature amended the law in order to confer immunity upon drugmakers in product liability suits where the FDA had approved the drug in question. *See Taylor*, 658 N.W.2d at 130 ("The 1995 amendment of the statute . . . provided that compliance with federal governmental standards (established by the FDA) is conclusive on the issue of due care for drugs."). The relevant provision states:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

M.C.L. § 2946(5). In addition to several qualifications not relevant to the case before us,[1] the immunity provision contains an important exception:

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[1] Michigan's law also states that the immunity "subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval." M.C.L. § 2946(5). And the immunity "does not apply if the defendant at any

> This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

M.C.L. § 2946(5)(a) (internal citations omitted). Hence, under these provisions, so long as a drug company did not withhold or misrepresent information that would have affected the FDA's approval of a putatively harmful drug, the company can successfully defend itself against products liability litigation by establishing that its product received the FDA's approval and complied with the FDA's labeling and substantive requirements.

B. Procedural History

Appellants in this case are all Michigan residents alleging injuries caused by Rezulin, a drug marketed and sold by Appellees for the treatment of Type-2 diabetes. The FDA originally approved Rezulin in 1997. After adverse liver-related effects were docu-

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time before the event that allegedly caused the injury . . . [m]akes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug." M.C.L. § 2946(5)(b).

mented in patients taking Rezulin, Appellees agreed to a series of label changes, which were authorized by the FDA on four occasions between November 1997 and June 1999. In March 2000, apparently at the FDA's request, *see Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 344 (2d Cir. 2003), Appellees withdrew Rezulin from the United States market.

The instant litigation began in state courts in Michigan and California. Appellants asserted various common law claims including, *inter alia*, breach of implied and express warranties, negligence, negligent misrepresentation, negligence *per se*, fraud, defective design, defective manufacturing, and loss of consortium. The drug companies removed the actions to federal court, and all of the claims were subsequently consolidated and transferred by the Judicial Panel on Multidistrict Litigation to Judge Lewis A. Kaplan in the Southern District of New York.

In the District Court, Appellees moved for judgment on the pleadings on the ground that liability was foreclosed under Michigan state law. To support their motion, Appellees emphasized *Buckman* and the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), which held (on the basis of *Buckman*) that the "fraud" exception in Michigan's statute was impliedly preempted by two federal laws —the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and the Medical Device Act ("MDA"), 21 U.S.C. §§ 360e(b)(1)(A)-(B)—and therefore had to be severed from the rest of the Michigan law.

The District Court agreed with Appellees, concluding that the immunity exception should be severed because under the reasoning of *Buckman*, it was pre-

empted by federal law.[2] The court gave two reasons for its decision. First, the District Court believed that, although it was not "absolutely bound" by *Garcia*, the Sixth Circuit's reasoning was owed "quite substantial deference" under *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981), a decision by a panel of this circuit which stated that conclusive deference should be given to a federal court of appeals' interpretation of the law of a state within its circuit. Second, "apart from *Factors*," the District Court reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again." Concluding that this would generate "a wholly impractical situation," the court held "that the exception in the Michigan statute is preempted, except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug approval process absent which approval would not have been granted." Hence, the court granted the drugmakers' motion for judgment on the pleadings and dismissed all of Appellants' complaints.

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[2] Before addressing the preemption issue, Judge Kaplan considered the choice-of-law question for those claims originally filed in California state court and concluded that there was "no serious argument for the application of California substantive law." In fact, the attorney representing those Michigan residents who filed suit in California conceded that he was the only tie his clients had to California. Moreover, Judge Kaplan observed that California's choice-of-law provisions required that the case be governed by the law of Michigan, where the plaintiffs reside and where the alleged injuries took place. None of the parties have challenged this finding on appeal.

Appellants filed a timely appeal.

DISCUSSION

We review *de novo* a district court's dismissal of a suit pursuant to a motion for judgment on the pleadings. *See King v. Am. Airlines, Inc.*, 284 F.3d 352, 356 (2d Cir. 2002); *Burnette v. Carothers*, 192 F.3d 52, 56 (2d Cir. 1999). "In deciding a Rule 12(c) motion, we apply the same standard as that applicable to a motion under Rule 12(b)(6), accepting the allegations contained in the complaint as true and drawing all reasonable inferences in favor of the nonmoving party." *Burnette*, 192 F.3d at 56.

This appeal raises two separate and significant questions. First, under the rule in *Factors*, must we follow our sister circuit's holding in *Garcia* because the Sixth Circuit's decision involved the laws of Michigan, a state within its circuit? Second, even if we are not required to defer conclusively to *Garcia*, should we nonetheless conclude, applying the logic of *Buckman*, that Appellants' common law claims—preserved by Michigan's exception—conflict with, and are therefore preempted by, federal law?

I.

The District Court interpreted *Factors* to mean that, although it was not "absolutely bound" by the Sixth Circuit's ruling, *Garcia* was owed "substantial deference." Appellees advocate an interpretation of *Factors* that insists upon more than deference. They contend that, under *Factors*, we are not free to reach a conclusion contrary to *Garcia* unless a different result is compelled by prior or subsequent pronouncements of

the Supreme Court of Michigan. For their part, Appellants do not identify any contrary Michigan law to refute the *Garcia* court's decision that federal law preempts Michigan's immunity exception.[3] As a result, Appellees maintain that *Garcia* binds us to dismiss Appellants' suit. Appellees may be correct in their reading of *Factors*, when it applies. But like the District Court they misgauge the relevance of *Factors* to the case before us.

Factors involved a contract dispute governed exclusively by Tennessee state law. In that context, we held that a federal court exercising diversity jurisdiction should give "conclusive deference" to "a ruling by a court of appeals deciding the law of a state within its circuit." *Factors*, 652 F.2d at 279. We elaborated that conclusive deference was owed except in very narrow circumstances:

> We need not and do not conclude that the state law holding of the pertinent court of appeals is automatically binding upon the federal courts of all the other circuits. The ultimate source for state law adjudication in diversity cases is the law as established by the constitution, statutes, or authoritative court decisions of the state. A federal court in another circuit would be obliged to disregard a state law holding by the pertinent court of appeals if persuaded that the holding had been superseded by a later pronouncement from state legislative or judicial sources, or that prior

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[3] Appellants' arguments against preemption rely mainly on federal precedent. The only Michigan case they focus on, *Maki v. East Tawas*, 188 N.W.2d 593 (Mich. 1971), bears solely on severability, not preemption.

> state court decisions had been inadvertently overlooked by the pertinent court of appeals.

Factors, 652 F.2d at 283 (internal citation omitted). Because neither of these circumstances applied to the sister circuit's decision—*i.e.*, the court of appeals' decision had not been weakened by subsequent developments in state law, nor was the decision contrary to prior state precedent—the *Factors* court mandated deference:

> Where, as here, the pertinent court of appeals has essayed its own prediction of the course of state law on a question of first impression within that state, the federal courts of other circuits should defer to that holding, perhaps always, and at least in all situations except the rare instance when it can be said with conviction that the pertinent court of appeals has disregarded clear signals emanating from the state's highest court pointing toward a different rule.

Factors, 652 F.2d at 283.

But *Factors* instructed us to defer conclusively to another circuit's judgment only when that court of appeals' decision addressed questions of *state* law from a state within that circuit. It asserted no obligation to defer to a foreign circuit's views on *federal* law. As to issues of federal law, we are permitted—indeed, required—to reach our own conclusions. *See Pan Am. World Airways, Inc. v. C. A. B.*, 517 F.2d 734, 741 (2d Cir. 1975) ("[W]e are not bound by the decision or the rationale of [another circuit] court."); *see also Colby v. J.C. Penney Co., Inc.*, 811 F.2d 1119, 1123 (7th Cir. 1987) ("We have an intermediate obligation to our sister federal courts of appeals. Bearing in mind the

interest in maintaining a reasonable uniformity of federal law and in sparing the Supreme Court the burden of taking cases merely to resolve conflicts between circuits, we give most respectful consideration to the decisions of the other courts of appeals and follow them whenever we can. Our district judges should, of course, do likewise with regard to such decisions . . . . But neither this court nor the district courts of this circuit give the decisions of other courts of appeals automatic deference; we recognize that, within reason, the parties to cases before us are entitled to our independent judgment." (internal citation omitted)).

This obligation does not change in the context of transferred cases. In *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993) (per curiam), we considered securities fraud claims that had been consolidated and transferred to the Southern District of New York only to be dismissed as untimely under our circuit's limitations guidelines. One set of claims, however, had originally been filed in the Southern District of Florida and would have been timely under the statute of limitations applicable under the Eleventh Circuit's rule (which would have borrowed Florida's "blue sky" limitations period). Thus, the question presented was "whether Second Circuit doctrine directs application of the Eleventh Circuit limitations rule to such a transferred action." *Menowitz*, 991 F.2d at 40. We stated that "[r]esolution of this question turns on whether the choice of the applicable limitations period is properly understood as a matter of state or of federal law." *Id.* Were it an issue of state law, we indicated that "a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed." *Id.* But since we concluded

that the proper statute of limitations applicable to a federal claim was a matter of federal law, we disregarded the Eleventh Circuit's approach to the federal issue and opted instead to follow our own. In so doing, we emphasized that, even in the transfer context, a court of appeals must develop its own circuit law on federal questions; it cannot mechanically adopt the reasoning and conclusions of its sister circuits:

> We have previously held that a transferee federal court should apply its interpretations of federal law, not the constructions of federal law of the transferor circuit. . . . [F]ederal courts comprise a single system applying a single body of law, and no litigant has a right to have the interpretation of one federal court rather than that of another determine his case.
>
> . . .
>
> [U]ntil the Supreme Court speaks, the federal circuit courts are under duties to arrive at their own determinations of the merits of federal questions presented to them; . . . [I]f a federal court simply accepts the interpretation of another circuit without [independently] addressing the merits, it is not doing its job.

Id. (internal citations and quotation marks omitted).

The problem, therefore, with the District Court's decision and with the position taken by Appellees is that both fail to appreciate that this appeal—unlike the Tennessee contract dispute in *Factors*—is not governed primarily, and certainly not exclusively, by state law. Rather, the question of whether federal law impliedly preempts part of Michigan's statutory scheme depends on significant issues of federal law including, *inter alia*, the meaning of Supreme Court

precedents, *e.g.*, *Buckman*, and the scope of federal statutes, *e.g.*, FDCA. As a result, in resolving this appeal, we operate under twin mandates with respect to the Sixth Circuit's opinion in *Garcia*. On the one hand, under *Factors*, we are bound to follow *Garcia*'s conclusions as to questions of Michigan state law. On the other hand, under *Menowitz*, we are obligated to answer independently questions of federal law, applying only the usual intercircuit regard for the Sixth Circuit's analysis of these federal issues.

Accordingly, the central question presented by this appeal—*i.e.*, whether federal law preempts Michigan's immunity exception—is controlled by the decision in *Garcia* only to the extent that the Sixth Circuit's conclusion rested solely on findings as to state law. *Garcia* did begin with an explanation of state law:

> [M.C.L. § 2946(5)] presents a somewhat different legal regime from the one invalidated in *Buckman*. The Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA rather than a specific cause of action for fraud on the FDA.

Garcia, 385 F.3d at 965-66 (internal footnote omitted). Under *Factors*, therefore, we must accept the Sixth Circuit's conclusion that M.C.L. § 2946(5) *does not* create a new cause of action for misleading the FDA. And that holding guides our review of the federal issues before us.[4]

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[4] It should be noted that *Factors*, a case involving Tennessee state law, was decided in 1981. At that time, the Tennessee Supreme Court did not accept certified questions. *See Holt by Holt v. Hypro, a Div. of Lear Siegler, Inc.*, 746 F.2d 353, 354 (6th Cir. 1984) ("We[, the Sixth

After issuing this interpretation of M.C.L. § 2946(5), the Sixth Circuit turned to issues of federal law. And, on the basis of *its* understanding of the Supreme Court's decision in *Buckman*, the Sixth Circuit concluded that the difference it had just identified —between those preexisting common law claims that survived M.C.L. § 2946(5) and those arising under a specific cause of action for fraud-on-the-FDA, like those invalidated in *Buckman*—was "immaterial." *See Garcia*, 385 F.3d at 966 ("As the [Michigan] district

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Circuit,] are somewhat puzzled by the [Tennessee] statute as it applies to minors injured by products over ten years old, and we sought to certify the question to the Tennessee Supreme Court. That Court has now advised us that they do not have the judicial power to accept certified questions. We are left to divine the meaning of the Tennessee Legislature on our own."). In fact, it was not until 1989 that Tennessee adopted a certification rule. *See* Tennessee Supreme Court Rule 23 ("The Supreme Court may, at its discretion, answer questions of law certified to it by the Supreme Court of the United States, a Court of Appeals of the United States, a District Court of the United States in Tennessee, or a United States Bankruptcy Court in Tennessee.") (made effective February 17, 1989). It may well be, therefore, that *Factors* would not foreclose us from certifying a question of state law to the relevant state court, even where the pertinent federal court of appeals has provided its interpretation.

We need not, and hence do not, however, decide in this case the significance of *Factors* when certification is available and appropriate. Certification to Michigan is available. *See* Michigan Court Rule 7.305(B)(1) ("When a federal court, state appellate court, or tribal court considers a question that Michigan law may resolve and that is not controlled by Michigan Supreme Court precedent, the court may on its own initiative or that of an interested party certify the question to the Michigan Supreme Court."). But *Garcia*'s holding that the state law at issue in this case does not *create* a new cause of action is so clearly correct, both on its face, and in view of the relationship of the current statute to the previous Michigan law (which allowed defendants to introduce evidence of compliance with government standards, *Taylor*, 658 N.W.2d at 130), that certification would not be appropriate.

court properly found, '*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.' ").

Nothing in *Factors* requires that we adopt the Sixth Circuit's reading of *Buckman*. On the contrary, because *Garcia*'s conclusions as to preemption depended on its analysis of federal (and not state) law, we must decide for ourselves whether Michigan's surviving common law cause of action is implicitly preempted by federal law under the rationale of *Buckman*. It is to this question that we, therefore, now turn.

II.

In *Buckman*, the Supreme Court considered whether federal law—specifically, the FDCA and the MDA —pre-empted state "fraud-on-the-FDA" claims. The plaintiffs in *Buckman* contended that a medical device manufacturer had obtained FDA approval for its product only after making fraudulent misrepresentations to the federal agency. Claiming that the FDA would not have approved the device but for these misrepresentations, the plaintiffs sought damages under California state law. The Court began by stating what is undoubtedly true that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (internal citation and quotation marks omitted). As a result, the presumption against federal preemption of a state law cause of action did not apply to fraud-on-the-FDA claims. *Id.*

In the absence of any presumption against preemption, the Court found that fraud-on-the-FDA claims conflicted with, and were therefore impliedly pre-

empted by, federal law. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. In other words, *policing fraud on the FDA* through a tort action could interfere with how the FDA might wish to police that kind of fraud itself.

The *Buckman* Court went on to express its concern that the potential conflict between federal law and the competing regulatory regimes of 50 states would unduly burden drug companies seeking to obtain FDA approval for their products. The Supreme Court worried that these companies, fearful of state liability, would file "a deluge of information" that the FDA does not require, thereby burdening the federal agency as well. *Id.* at 351. But the Court ended by emphasizing that the plaintiffs' claims before it were not rooted in traditional state law, and were instead derivative of federal law:

> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of . . . federal enactments is a critical element in their case.

Id. At 353. For these reasons, the Court invalidated the plaintiffs' fraud-on-the-FDA claims as impliedly preempted by federal law.

Echoing the conclusion of the Sixth Circuit, Appellees argue that, notwithstanding *Garcia*'s statement that M.C.L. § 2946(5) did not create "a specific cause of action for fraud on the FDA," *Garcia*, 385 F.3d at

966, there is no meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law. We disagree. There are three differences between the nature of the claim which M.C.L. § 2946(5) exempts from abolition and the claim in *Buckman*. Given the bases of *Buckman*'s holding, each of these is crucial.

A. *Presumption Against Preemption*

First, the presumption against federal preemption of state law obtains in the case before us. In *Medtronic*, the Supreme Court explained that "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485. In *Buckman*, the Court held that this presumption did not apply *because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." Buckman*, 531 U.S. at 347 (internal citation and quotation marks omitted) (emphasis added).

In the case before us, instead, the cause of action (which survives the changes made by M.C.L. § 2946(5)) cannot reasonably be characterized as a state's attempt to police fraud against the FDA. And, significantly, *Garcia* did not so characterize it. Rather, as *Garcia* recognized, M.C.L. § 2946(5) did not invent new causes of action premised on fraud against the FDA. The object of the legislative scheme was rather to regulate and restrict when victims could continue to recover under preexisting state products liability law.[5]

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[5] We also have found no evidence that the goal of preventing or punishing fraud against the FDA in any way motivated Michigan legislators to enact the statutory framework in question. M.C.L.

The Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to "regulat[e] matters of health and safety," which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest. *See Buckman*, 531 U.S. at 348 (citing *Medtronic*, 518 U.S. at 485 as governing "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' " and contrasting these to the case before it). As a result, while there may be reasons to override that presumption, the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*.[6]

B. Traditional Common Law Liability

Second, Appellants here are not pressing "fraud-on-the-FDA" claims, as the plaintiffs in *Buckman* were understood by the Supreme Court to be doing. They are, rather, asserting claims that sound in traditional state tort law. In *Buckman*, the Supreme Court mentioned two characteristics of preempted "fraud-on-the-

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§ 2946(5) grew out of Michigan Senate Bill 344; the "Bill Analysis," produced by the state Senate Fiscal Agency, suggests that the main impetus driving the legislation was a desire to limit the liability of drug makers under state tort law. *See generally* S. Fiscal Agency, SFA B. Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at *1 (Jan. 11, 1996) ("According to many, over the past several decades there has been an explosion of product liability litigation, resulting in unfair and excessive judgments against manufacturers and sellers.... In Congress and state legislatures, a number of proposals have been advanced to reduce manufacturers' and sellers' exposure to liability.").

[6] This fact also substantially diminishes the persuasive effect of the federal law analysis made in *Garcia*, since the Sixth Circuit's holding in *Garcia* was based on the assumption that no presumption against preemption applied.

FDA" claims that distinguish them from claims sounding in preexisting common law.

The *Buckman* Court suggested that the source and "vintage" of the *duty* the drug maker is accused of breaching in "fraud-on-the-FDA" claims is different from the source and "vintage" of the duty that obtains in traditional tort claims. On this basis, the *Buckman* Court distinguished the plaintiff's unpreempted claims in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), from those before it and wrote: "Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Buckman*, 531 U.S. at 352.

Significantly, all of the claims advanced by Appellants in this case are premised on traditional duties between a product manufacturer and Michigan consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency. As a result, were we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers. We see no reason, nor can we identify any precedent, to justify such a result.[7]

The second difference between common law actions and "fraud-on-the-FDA" claims, suggested in *Buckman*, is that in FDA-fraud cases, proof of fraud against the FDA is *alone sufficient* to impose liability. In

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[7] This may be seen as another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case.

Buckman, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements. And *Buckman* explicitly distinguished *Medtronic* on this ground. *Medtronic*, the *Buckman* Court said, involved a "common-law negligence action against the manufacturer of an allegedly defective" product:

> [T]he *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not *solely* from the violation of FDCA requirements. In the present case, however, the fraud claims exist *solely* by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that *any* violation of the FDCA will support a state-law claim.

Buckman, 531 U.S. at 352-53 (emphasis added) (internal citation omitted).

As in *Medtronic*, the plaintiffs' claims in the case before us "parallel federal safety requirements" but are not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements. On the contrary, the plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime. These pre-existing common law claims survive under M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA. Given *Buckman*'s explanation of *Medtronic*, *Buckman* cannot be read as

precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA.

Significantly, this reading of *Buckman* reflects the position the pharmaceutical industry articulated at oral argument in *Buckman*. Thus, the industry's presentation to the Supreme Court began by stressing the unusual and narrow claim before the *Buckman* Court:

> The plaintiffs in this case are people who underwent back surgery in which particular medical devices were used. They brought this suit under State law to recover for injuries allegedly caused by their—by these devices, but this is a very unusual form of State law product liability action. The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeons who used these devices did anything wrong. There's no claim here of medical malpractice.
>
> Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices, that, absent this deception, these devices would never have been on the market, and that, if the devices had never have been on the market, they wouldn't have been used in their surgeries and they wouldn't have suffered any injuries.

Oral Argument Transcript, *Buckman*, 531 U.S. 341, 2000 WL 1801621, at *3-4 (2000) (No. 98-1768).[8]

C. Immunity as Affirmative Defense

Third, and once more unlike *Buckman*, the Michigan Supreme Court has indicated that proof of fraud against the FDA is not even an *element* of a products liability claim like the one here brought. The existence of properly-obtained FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature in M.C.L. § 2946(5). *See Taylor*, 658 N.W.2d at 131. Thus, in *Taylor*'s discussion of M.C.L. § 2946(5), Michigan's highest court offered this characterization of the statute: "[A] manufacturer or seller of a drug that has been approved by the FDA has an absolute *defense* to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller." *Id.* (emphasis added). And, throughout its opinion, the *Taylor* court spoke of the *defendant's* references to the *FDA's* findings, suggesting again that it is the defendant that must invoke the FDA's decision to approve its drug if it wishes to

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[8] Similarly, a second lawyer for the industry indicated that traditional tort remedies were *not* implicated by *Buckman*. When asked about what remedies an injured plaintiff would have under his theory of the case, the attorney responded: "The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available . . . ." *Id.* at 21 (emphasis added). In the case before us, Appellants have asserted precisely "negligent design, negligent manufacturing, [etc.] . . ." and claim only that the Michigan exclusion from liability does not apply to their traditional tort law claims because there was *also* fraud on the FDA.

insulate itself from liability, *Taylor*, 658 N.W.2d at 134. We take this to mean that the Michigan law in question does no more than create a defense that drug makers may invoke, if they so decide, and that it is not up to the plaintiff to prove fraud as an element of his or her claim.

Finding preemption of traditional common law claims where fraud is not even a required element—but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law—would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect. *See Medtronic*, 518 U.S. at 485 ("[P]articularly in [circumstances] in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the *clear and manifest* purpose of Congress.'" (internal citations omitted) (emphasis added)).

* * *

The *Buckman* Court did, however, mention practical concerns with allowing "fraud-on-the-FDA" suits to go unpreempted. Specifically, it said that permitting such suits would result in a deluge of information that could swamp FDA administrators. The *Garcia* court, in applying *Buckman* to a suit like the one before us, made reference to these same concerns. But these worries, if deemed controlling, would prove too much.

They would result in preemption of a scope that no one is contemplating, let alone advocating.

In terms of deluging the FDA, there is little difference between (a) causes of action, like the instant one, where proof of fraud against the FDA is not the basis of the cause of action but is necessary to negate a limitation on state liability, and (b) causes of action where proof of fraud against the FDA is permitted but not conclusive (as it was under the precursor to the Michigan law at issue here, *see supra*, and as it presumably is in most states in the country). So long as a court or jury is *allowed to consider* evidence of fraud against the FDA in an ordinary common law tort suit, and so long as juries are likely to react to such evidence, there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* Courts. Requiring such evidence when a plaintiff seeks to counter a statutory defense from liability would not significantly alter that incentive. Only when proof of fraud is by itself *sufficient* to impose liability—and indeed is the sole basis of liability (as it was in *Buckman*)—does the incentive to flood the FDA appreciably escalate.

In other words, the incentive to supply additional data to the FDA under the Michigan law before us is no greater than the incentive that exists whenever evidence of what a company submitted, or failed to submit, to the FDA is admissible and probative of liability. It follows that under *Garcia*'s reading of *Buckman*, unless a state barred the submission of evidence of fraud against the FDA in run of the mill tort cases, the policy concerns that *Buckman* expressed in a very narrow context would seemingly justify invalidating any product liability suit brought against

a drugmaker. We do not believe *Buckman* meant to go anywhere near so far.[9]

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[9] Since we heard oral argument in this case, the FDA issued a final rule governing the content and format of drug product labeling. *See* 71 Fed. Reg. 3922 (Jan. 24, 2006). In the amended regulation, the FDA announced its view that FDA labeling requirements preempt state law claims that impose additional or different requirements: "[The] FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." *Id.* at 3934. In so doing, the FDA apparently confined its view that state claims undermine federal law to circumstances "when [state laws] purport to compel a firm to include in labeling or advertising a statement that [the] FDA has considered and found scientifically unsubstantiated." *Id.* at 3935.

Although any statement by a federal agency carries persuasive weight, the FDA's recent pronouncement does not ultimately affect our analysis in this case. The FDA's statement concerns only preemption of state laws that impose additional *labeling* requirements. Appellants' claims rest on far broader allegations, *e.g.*, defective design and manufacturing.

To the extent that the FDA's statement might bear peripherally on the claims asserted in this case, it is not clear what, if any, deference would be owed to the FDA's view. Assertions of implied preemption arguably originate in statutory ambiguity as to which an agency's interpretations may be accorded deference. *See generally Chevron U.S.A, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984). And—at least in a field of regulation in which no presumption against preemption applies—we recently indicated that we will give *Chevron* deference to an agency's regulation even though its interpretation has the resultant effect of preempting state law. *See Wachovia Bank, N.A. v. Burke*, 414 F.3d 305, 314-15 (2d Cir. 2005).

But, whatever deference would be owed to an agency's view in contexts where a presumption against federal preemption does apply, it is arguable that an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption. *Cf. Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself."). Because we find that a presumption against preemption applies in the instant case, it may also be argued that even

III.

Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. *Buckman* underscored this fact, finding implied preemption of a newly-fashioned state cause of action only where (1) no presumption against federal preemption obtained, and (2) the cause of action, by assigning liability *solely* on the basis of fraud against the FDA, imposed significant and distinctive burdens on the FDA and the entities it regulates. The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims. In the presence of this presumption, because Michigan law does not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman*, and because Appellants' lawsuits depend primarily on traditional and preexisting tort sources, not at all on a "fraud-on-the-FDA" cause of action created by state law, and only incidentally on evidence of such fraud, we conclude that the Michigan immunity exception is not prohibited through preemption. It follows that common law liability is not foreclosed by federal law, and Appellants' claims should not have been dismissed.

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in the face of an FDA statement asserting preemption, the common law claims preserved by Michigan's immunity exception cannot be preempted by federal law absent a clear statement from Congress. In any event, since no such FDA statement dealing with Appellants' claims has been made, the question of its effect, were one to issue, is not before us.

For the foregoing reasons, we VACATE the District Court's grant of judgment on the pleadings, and we REMAND the case to the District Court for further proceedings.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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00 Civ. 2843 LAK
February 24, 2005 10:12 a.m.

IN RE: REZULIN

Before:

HON. LEWIS A. KAPLAN,
District Judge

APPEARANCES

RYAN M. MCNAMARA,
J. DOUGLAS PETERS,
KAREN E. KOSKOFF,
Attorneys for plaintiffs

DAVID KLINGSBERG,
WENDY S. DOWSE,
BERT L. SLONIM,
Attorneys for defendants

So far as the footnote to which plaintiffs' counsel referred, I think that while the Court of Appeals referred to the lack of evidence, as your Honor recognized when the court then went on to decide this not on the basis of evidence, but on the basis of the unconstitutionality and severance of the provision, that that all went by the boards and became irrelevant.

We suggest that, respectfully, that the motion should be granted because of the Garcia controlling authority and severing out that part of the statute, and there is no allegation and, indeed, could not be any allegation, to meet Garcia's interpretation of the Michigan statute, that there is a federal FDA finding of fraud on the FDA which was intentional and which would have led to withdrawal of the drug.

Thank you.

THE COURT: Thank you.

The argument is very helpful and I am prepared to rule now, although I reserve the right to edit the transcript so that it makes sense in writing as well as spoken English.

(Recess)

THE COURT: We deal here with 7 of the many hundreds of individual product liability actions that are consolidated for pretrial purposes before me by the Multidistrict Panel, and specifically with the claims of approximately 178 plaintiffs, each of whom ingested Rezulin and each of whom at all relevant times was a resident of Michigan.

One or more of these cases was filed in California. The rest were filed in Michigan. All were transferred here by the Multidistrict Panel. Michigan has an interesting statute which is the basis of the defendants' motion. Section 600.2946 (5) of Michigan compiled laws provides, in substance, that no drug manufacturer may

be held liable in a product liability case based on a drug if the drug was approved for safety and efficacy by the Food & Drug Administration and the drug was properly labeled.

The statute is subject to two exceptions:

First, the immunity conferred by the statute does not apply, "if the manufacturer intentionally withheld or misrepresented material information concerning the drug that is required to be submitted under the Food, Drug & Cosmetics Act, and the drug would not have been approved or the FDA would have withdrawn approval if the information was accurately submitted to the FDA; or if the manufacturer bribed an FDA official or employee to secure the drug's approval.

The second exception applies where the offending drug was sold after the FDA withdrew approval or ordered the drug removed from the market.

It is the first of these exceptions that is at issue here, as the manufacturer here moves for judgment on the pleadings, dismissing the complaints of all of the Michigan plaintiffs, including those who filed in California, and the plaintiffs seek to bring themselves within the first of the exceptions I have mentioned, which I am going to refer to by the shorthand of the fraud on the FDA exception.

The first issue is a matter of choice of law. All of the plaintiffs who are represented by counsel from Michigan or elsewhere other than California, concede that Michigan law governs. The plaintiffs who are represented by the Girardi firm in Los Angeles contend that I should apply California law; and, therefore, need not concern myself with the Michigan statute. They rely on the assertion that I am to apply under what they say are settled principles the law of the forum state even after transfer.

They've got it all wrong. In an earlier decision in this case, reported at 210 Federal Rules Decision 61, decided in 2002, I stated what the principles of law referred to actually are, whereas here a case is transferred, the transferee court applies the choice of law rules of the transferrer court.

Accordingly, with respect to those plaintiffs who filed in California, I am to apply California choice of law rules, I am to apply California substantive law if and only if under the law of California governing choice of law, California would apply its own substantive law.

There is, in fact, no serious argument for the application of California substantive law. The plaintiffs who make this argument were residents of Michigan at all relevant times. The only connection between California and those plaintiffs is the fact that they happen to hire lawyers in California who brought suit in California.

As much as I am in favor, as I indicated in argument, of lawyers making livings, that just isn't good enough. Michigan's interests on anybody's analysis outweigh California's, which are trivial. So I apply Michigan substantive law to the claims of all of the plaintiffs.

The question, therefore, is whether the plaintiffs, assuming they have adequately pled fraud on the FDA, should be afforded an opportunity to try to prove it in this court.

The starting point for this analysis, in my view, and I think everybody else's, is the Supreme Court's decision four years ago in this week, Buckman Company versus Plaintiffs' Legal Committee, 541 U.S. 341 (2001). In that case, plaintiffs brought an action or actions against a manufacturer of orthopedic bone screws, claiming that the manufacturers had committed fraud on the FDA.

They sought recovery on the ground that the manufacturer's fraud on the FDA was a breach of duty and a

cause of the injuries that the plaintiffs had suffered. Their theory was that if the FDA had been told the truth, to put it in colloquial terms, it would not have approved the bone screws, the plaintiffs wouldn't have had them implanted; and, therefore, the plaintiffs wouldn't have been injured.

In a 7-to-2 decision, the United States Supreme Court held that there could be no recovery on a theory of fraud on the FDA because the Food, Drug & Cosmetic Act preempted the matter of fraud on the FDA. It reached its conclusion after noting that allowing state law tort claims based on fraud on the FDA would, and now I quote:

"Conflict with the FDA's responsibility to police fraud consistently with the administration's judgment and objectives. As a practical matter, compliance with the FDA's detailed legislature regime in the shadow of 50 states' tort regimes will dramatically increase the burdens facing potential applicants" for FDA approval, 531 U.S., at 350.

The court indicated it might deter applicants from seeking approval of medical devices under Section 510(k) of the Food, Drug & Cosmetics Act, as amended by the Medical Devices Amendments of 1976, for fear that seeking such approval would expose them to liability.

The court relied also on its view that allowing state law tort claims based on fraud on the FDA theories could cause applicants to deluge the FDA with unwanted information to protect against state law fraud on the FDA claims.

The second piece of the puzzle is the 6th Circuit's decision in October in Garcia versus Wyeth-Ayerst Laboratories, 385 Fed 3rd. 961. The plaintiff in that case, a Michigan plaintiff who sued in Michigan, brought a

products liability suit against a drug manufacturer based on her having ingested a nonsteriodal, anti-inflammatory drug known as Duract, which allegedly had caused liver failure and led to a liver transplant in order to save the life of the plaintiff. Interestingly, as in this case, the manufacturer voluntarily had withdrawn the drug from the market by the time the case was decided.

The defendant in Garcia moved for summary judgment, dismissing the case on the basis of the Michigan statute that is at issue here. The 6th Circuit, relying on Buckman, held that the fraud on the FDA exception to the Michigan statute upon which the plaintiff in Garcia relied was impliedly preempted for the same reasons as the tort remedy at issue in Buckman was preempted.

The circuit said that to allow plaintiffs in strict products liability actions in Michigan to seek to avoid the effect of the statute by coming within the fraud on the FDA exception would conflict with the FDA's responsibility to police fraud and threaten to increase burdens on applicants seeking to avoid losing the exception, or at least it alluded to those concerns previously expressed by the Supreme Court in Buckman.

The court then went on to consider whether the legislation was severable. Although it may not have put it in precisely these terms, the issue before it was whether, given the unconstitutionality of the fraud on the FDA exception, the Michigan legislature rather would have a system in which there was blanket immunity for FDA-approved drugs, immunity in the absence of a finding by the FDA or some federal forum, anyway, of fraud or no immunity for FDA approved drugs at all.

The 6th Circuit rejected the no immunity option, and it concluded that—just give me one moment—the exception was preempted except in circumstances where there had been a finding by the FDA of fraud.

Now, there is no doubt that that outcome as a matter of social policy could perhaps be criticized by reasonable people. I assume, although I have no direct knowledge of it, the truth of what counsel for some of the plaintiffs said; namely, that the FDA simply does not go around suing people or otherwise seeking to obtain or making findings that drug manufacturers have committed fraud in the new drug application process.

The 6th Circuit's conclusion, therefore, puts plaintiffs who are subject to the Michigan statute in a pretty difficult spot. It may be that that is an undesirable outcome and it may well be that Congress and/or the Michigan legislature ought to address it, and Mr. Peters was kind enough to inform me that perhaps both are doing so. But it is, frankly, none of my affair for several reasons:

First of all, in Factors, et cetera, versus Pro Arts, Inc., 652 F.2d 278, at 283 (2d Cir. 1981), the Second Circuit has made it clear that although I am not absolutely bound by the 6th Circuit's ruling, I ought to give it quite substantial deference.

The second reason is that even apart from Factors, et cetera, I think the 6th Circuit is right in its application of Buckman in this circumstance. Indeed, I think that the case for preemption, at least to the extent that I have indicated; namely, preemption, that would foreclose the fraud on the FDA exception to the statute in the absence of a finding by the FDA or in an action brought by the FDA that a material fraud resulted in the approval of the FDA—sorry. I lost the threaded sentence.

(Record read)

THE COURT: Is even stronger than the 6th Circuit made, and I think that some of the colloquy that we had here this morning really illustrates it. If plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits,

whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again.

I recognize that over time there would be a reduction in the extent to which that might occur by virtue of application of principles of collateral estoppel, res judicata, but the fact of the matter is that for some significant period of time at the beginning of every cycle of new drug litigation, the question would arise over and over again, often in all 50 states, often in every county in America, as to whether the FDA had been defrauded in the new drug application process.

The Food and Drug Administration would become the Food, Drug & Litigation Administration. The interference with the proper discharge of the mission that Congress created the FDA to perform would be enormous. It's just a wholly impractical situation, and so I, too, conclude that the exception in the Michigan statute is preempted, except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug approval process absent which approval would not have been granted.

Accordingly, the defendants' motion for summary judgment on the pleadings dismissing the complaints in these actions is granted.

Now, I will always invite counsel, if I made some mistake of fact or I have overlooked some legal argument that somebody thinks I ought to address, please tell me now and I'll try to address it if I think it is appropriate. Otherwise, I am not inviting reargument, but if there is something that is going to produce a motion for reargument next week, I would like to know it now and save you the trouble.

MR. PETERS: It is a small fact. The court said 178 cases. It might be 187 cases being dismissed.

THE COURT: All right. I stand corrected, and it is plaintiffs; it is not cases, right?

MR. PETERS: Plaintiffs.

MR. KLINGSBERG: Recipients of the drug.

THE COURT: I have 7 complaints with 187 plaintiffs.

MR. PETERS: Correct.

THE COURT: All right. Well, I thank you very much. I hope, Mr. Peters, you enjoy the show up in Central Park.

MR. KLINGSBERG: There are more plaintiffs because sometimes if there is a decedent, you get relatives, 187 people who were recipients of the Rezulin.

THE COURT: That is close enough for this purpose.

(Court adjourned)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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00 Civ. 2843 (LAK)

In re:

REZULIN PRODUCTS LIABILITY LITIGATION
(MDL No. 1348)

This Document Relates to: 00 Civ. 5117,
01 Civ. 0050, 01 Civ. 2242, 01 Civ. 9817,
03 Civ. 3488, 04 Civ. 3957, 04 Civ. 10031

PRETRIAL ORDER NO. 355
(Michigan Plaintiffs - Motion for
Judgment on the Pleadings)

LEWIS A. KAPLAN, *District Judge.*

Defendants' motion for judgment on the pleadings dismissing the complaints [00 Civ. 2843, docket item 2798) is granted for the reasons stated on the record in open court this day.

SO ORDERED.

Dated: February 24, 2005

/s/ LEWIS A. KAPLAN
Lewis A. Kaplan
United States District Judge

[LETTERHEAD OF UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT]

Filed February 12, 2007

Date:	
Docket Number:	05-1705-cv
Short Title:	Desiano v. Warner Lambert Co.
DC Docket Number:	00-cv-2843
DC:	SDNY (NEW YORK CITY)
DC Judge:	Honorable Lewis Kaplan

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 12th day of February two thousand seven.

Caesar Desiano, ET AL.,

Plaintiffs-Appellants,

—v.—

Warber-Lambert Company, ET AL.,

Defendants-Appellees.

A petition for panel rehearing and a petition for rehearing en banc having been filed herein by the Defendants-Appellees Warner-Lambert Company LLC and Pfizer Inc. Upon consideration by the panel that decided the appeal, it is Ordered that said petition for rehearing is DENIED.

It is further noted that the petition for rehearing en banc has been transmitted to the judges for the court in regular active service and to any other judge that heard the appeal and that no such judge has requested that a vote be taken thereon.

For the Court,

Thomas Asreen, Acting Clerk

By: /s/ [ILLEGIBLE] HELLER
Motion Staff Attorney

U.S. CONT. art. VI, cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

MICH. COMP. LAWS § 600.2946

§ 600.2946. Product liability action; admissible evidence

. . .

(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

21 U.S.C. § 332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown[,] to restrain violations of section 331of this title, except paragraphs (h), (i), and (j).

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

21 U.S.C. § 333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1), if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both.

(b) Prescription drug market violations

(1) Notwithstanding subsection (a), any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than $100,000.

(4) (A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section

331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and con-

viction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 384(b) of this title and knowingly fails to comply with a requirement of section 384(e) of this title that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a), (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter, or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not,

under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary, under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) of this title nor section 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food

No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section § 331 of this title involving misbranded food if the violation

exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising.

(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by Title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under section 413 of such Act.

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f) Redesignated (g)

(g) Violations related to devices

(1) (A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $ 15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 374(g) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 360i(a) or 360j(f) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 360i(e) or (f) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2) (A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 342(a)(2)(B) of this title shall be subject to a civil money penalty of not more than

$50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section § 334 of this title or the injunction authorities of section 332 of this title with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 346a(g)(2)(B) of this title. The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.

(3) (A) A civil penalty under paragraph (1) or (2) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the atten-

dance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1) or (2). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(4) Any person who requested, in accordance with paragraph (3)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(5) If any person fails to pay an assessment of a civil penalty—

> (A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (4), or

(B) after a court in an action brought under paragraph (4) has entered a final judgment in favor of the Secretary, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (4) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

21 U.S.C. § 334. Seizure

(a) Grounds and jurisdiction

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties,

or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and (D) Any adulterated or misbranded device.

(3) (A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

(i) is misbranded under section 343(a)(2) of this title because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i) (I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) [21 USCS § 343(a)(2)] was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

(b) Procedure; multiplicity of pending proceedings

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice

and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) Availability of samples of seized goods prior to trial

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures

(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or dis-

posed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 381(e) of this title can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6) of this title, section 351(a)(3) of this title, section 352(j) of this title, or section 361(a) or (d) of this title. Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 381(e)(1)(A), (B) of this title and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(e) of this title have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section § 344 or 355 of this title be introduced into

interest to commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) Costs

When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) Removal of case for trial

In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is

to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) Administrative restraint; detention orders

(1) If during an inspection conducted under section 374 of this title of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 332 of this title, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2) (A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) released by the Secretary, or

(ii) the expiration of the detention period applicable to such order, whichever occurs first.

(B) A device subject to a detention order under paragraph (1) may be moved—

(i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.

(h) Administrative detention of foods

(1) Detention authority

(A) In general

An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act [21 USCS §§ 301 et seq.] conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(B) Secretary's approval

An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this chapter in which the article involved is located, or is an official senior to such director.

(2) Period of detention

An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302 [21 USCS § 332]. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) Security of detained article

An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 381(b) of this title does not autho-

rize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) Appeal of detention order

(A) In general

With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) Effect of instituting court action

The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 332 of this title regarding the article of food involved.

21 U.S.C. § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

. . .

21 U.S.C. § 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c 343. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the

applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of

the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice. An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) Timing of notice. An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice. An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) Contents of notice. A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4) (A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or sub-

section (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of title 42 (including all scientific and medical matters, chemistry, manu- facturing, and controls).

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional

period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it

was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under

paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any

substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i);

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of title 28, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action. If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have

been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application. For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to per-

sons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E) (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any

ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of

patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984 and the supplement contains reports of new clinical investigations (other than bioavailabilty [bioavailability] studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective

before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information

before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the

Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application sub-

mitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such addi-

tional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests

(including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3) (A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2) (A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii) (I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture,

use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D) (i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part

of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C) (i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title or no petition

to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D) (i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those

of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has

been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or (K) the application contains an untrue statement of material fact.

(5) (A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Sec-

retary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction pro-

hibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug

under subparagraph (F) or section 355a of this title or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the

patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph

(2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or (bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the

180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determi-

nation by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph

(2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in

paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F) (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of

this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984 and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which

refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7) (A) (i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A) (i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Public disclosure of safety and effectiveness data

Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n) Scientific advisory panels

(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 262 of title 42, the Sec-

retary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act [21 USCS

§§ 301 et seq.] may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, for

persons in the Government service employed intermittently.

(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

21 U.S.C. § 372. Examinations and investigations

(a) Authority to conduct

(1) The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(2) (A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this chapter through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

(B) A memorandum of understanding under subparagraph (A) between the Secretary and another Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

(C) For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year—

(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.

(3) In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this chapter, the facilities at his disposal will permit of such inspection.

(4) For the purposes of this subsection, the term "United States" means the States and the District of Columbia.

(b) Availability to owner of part of analysis samples

Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Secretary shall, upon request, provide a part of such official sample for exam-

ination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) Records of other departments and agencies

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection.

(d) Information on patents for drugs

The Secretary is authorized and directed, upon request from the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

(e) Powers of enforcement personnel

Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this chapter relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 334 of this title;

(4) make arrests without warrant for offenses under this chapter with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 334(a)(2) of this title, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 334(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 334(a)(2) of this title shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

21 U.S.C. § 393. Food and Drug Administration

. . .

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

. . .

(B) human and veterinary drugs are safe and effective;

. . .

21 C.F.R. § 10.30. Citizen petition

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with § 10.20 and in the following form:

(Date) _____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

CITIZEN PETITION

The undersigned submits this petition under (relevant statutory sections, if known) of the (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording

of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(A) claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information

known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Division of Dockets Management will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Division of Dockets Management on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e) (1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and

the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. The petitioner is to be notified in writing of the Commissioner's decision. The decision will be placed in the public docket file in the office of the Division of Dockets Management and may also be in the form of a notice published in the FEDERAL REGISTER.

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.

(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under parts 12, 13, 14, or 15. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under parts 12, 13, 14, 15, or 16.

(3) A FEDERAL REGISTER notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with § 10.40 or § 12.20.

(5) Any other specific public procedure established in this chapter and expressly applicable to the matter.

(i) The record of the administrative proceeding consists of the following:

(1) The petition, including all information on which it relies, filed by the Division of Dockets Management.

(2) All comments received on the petition, including all information submitted as a part of the comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from the optional procedures specified in paragraph (h) of this section, except a transcript of a closed portion of a public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(6) All documents filed with the Division of Dockets Management under § 10.65(h).

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in § 10.33(k) or § 10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(l) The Division of Dockets Management will maintain a chronological list of each petition filed under this section and § 10.85, but not of petitions submitted elsewhere in the agency under § 10.25(a)(1), showing:

(1) The docket number;

(2) The date the petition was filed by the Division of Dockets Management;

(3) The name of the petitioner;

(4) The subject matter involved; and

(5) The disposition of the petition.

21 C.F.R. § 314.50. Content and format of an application

Applications and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. Three copies of the application are required: An archival copy, a review copy, and a field copy. An application for a new chemical entity will generally contain an application form, an index, a summary, five or six technical sections, case report tabulations of patient data, case report forms, drug samples, and labeling, including, if applicable, any Medication Guide required under part 208 of this chapter. Other applications will generally contain only some of those items, and information will be limited to that needed to support the particular submission. These include an application of the type described in section 505(b)(2) of the act, an amendment, and a supplement. The application is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source. FDA will maintain guidance documents on the format and content of applications to assist applicants in their preparation.

(a) Application form. The applicant shall submit a completed and signed application form that contains the following:

(1) The name and address of the applicant; the date of the application; the application number if previously issued (for example, if the application is a resubmission, an amendment, or a supplement); the name of the drug product, including its established, proprietary, code, and

chemical names; the dosage form and strength; the route of administration; the identification numbers of all investigational new drug applications that are referenced in the application; the identification numbers of all drug master files and other applications under this part that are referenced in the application; and the drug product's proposed indications for use.

(2) A statement whether the submission is an original submission, a 505(b)(2) application, a resubmission, or a supplement to an application under § 314.70.

(3) A statement whether the applicant proposes to market the drug product as a prescription or an over-the-counter product.

(4) A check-list identifying what enclosures required under this section the applicant is submitting.

(5) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. If the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a

(b) Index. The archival copy of the application is required to contain a comprehensive index by volume number and page number to the summary under paragraph (c) of this section, the technical sections under paragraph (d) of this section, and the supporting information under paragraph (f) of this section.

(c) Summary.

(1) An application is required to contain a summary of the application in enough detail that the reader may gain a good general understanding of the data and informa-

tion in the application, including an understanding of the quantitative aspects of the data. The summary is not required for supplements under § 314.70. Resubmissions of an application should contain an updated summary, as appropriate. The summary should discuss all aspects of the application, and synthesize the information into a well-structured and unified document. The summary should be written at approximately the level of detail required for publication in, and meet the editorial standards generally applied by, refereed scientific and medical journals. In addition to the agency personnel reviewing the summary in the context of their review of the application, FDA may furnish the summary to FDA advisory committee members and agency officials whose duties require an understanding of the application. To the extent possible, data in the summary should be presented in tabular and graphic forms. FDA has prepared a guideline under § 10.90(b) that provides information about how to prepare a summary. The summary required under this paragraph may be used by FDA or the applicant to prepare the Summary Basis of Approval document for public disclosure (under § 314.430(e)(2)(ii)) when the application is approved.

(2) The summary is required to contain the following information:

(i) The proposed text of the labeling, including, if applicable, any Medication Guide required under part 208 of this chapter, for the drug, with annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling, and, if the application is for a prescription drug, statements describing the reasons for omitting a section or sub-

section of the labeling format in § 201.57 of this chapter.

(ii) A statement identifying the pharmacologic class of the drug and a discussion of the scientific rationale for the drug, its intended use, and the potential clinical benefits of the drug product.

(iii) A brief description of the marketing history, if any, of the drug outside the United States, including a list of the countries in which the drug has been marketed, a list of any countries in which the drug has been withdrawn from marketing for any reason related to safety or effectiveness, and a list of countries in which applications for marketing are pending. The description is required to describe both marketing by the applicant and, if known, the marketing history of other persons.

(iv) A summary of the chemistry, manufacturing, and controls section of the application.

(v) A summary of the nonclinical pharmacology and toxicology section of the application.

(vi) A summary of the human pharmacokinetics and bioavailability section of the application.

(vii) A summary of the microbiology section of the application (for anti-infective drugs only).

(viii) A summary of the clinical data section of the application, including the results of statistical analyses of the clinical trials.

(ix) A concluding discussion that presents the benefit and risk considerations related to the drug, including a discussion of any proposed additional studies or surveillance the applicant intends to conduct postmarketing.

(d) Technical sections.

The application is required to contain the technical sections described below. Each technical section is required to contain data and information in sufficient detail to permit the agency to make a knowledgeable judgment about whether to approve the application or whether grounds exist under section 505(d) of the act to refuse to approve the application. The required technical sections are as follows:

(1) Chemistry, manufacturing, and controls section. A section describing the composition, manufacture, and specification of the drug substance and the drug product, including the following:

(i) Drug substance. A full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability, sterility, particle size, and crystalline form. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative sources, process controls, and analytical procedures. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(ii) (a) Drug product. A list of all components used in the manufacture of the drug product (regardless of whether they appear in the drug product) and a statement of the composition of the drug product; the specifications for each component; the name and address of each manufacturer of the drug product; a description of the manufacturing and packaging procedures and in-process controls for the drug product; the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product, including, for example, tests, analytical procedures, and acceptance criteria relating to sterility, dissolution rate, container closure systems; and stability data with proposed expiration dating. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative components, manufacturing and packaging procedures, inprocess controls, and analytical procedures. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(b) Unless provided by paragraph (d)(1)(ii)(a) of this section, for each batch of the drug product used to conduct a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter or used to conduct a primary stability study: The batch production record; the specification for each component and for the drug product; the names and addresses of the sources of the active and noncompendial inactive components and of the container and closure system for the drug product; the name and address of each contract facility involved in the manufacture, processing, packaging, or testing of the drug product and identification of the operation

performed by each contract facility; and the results of any test performed on the components used in the manufacture of the drug product as required by § 211.84(d) of this chapter and on the drug product as required by § 211.165 of this chapter.

(c) The proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product or a comparably detailed description of the production process for a representative batch of the drug product.

(iii) Environmental impact. The application is required to contain either a claim for categorical exclusion under § 25.30 or 25.31 of this chapter or an environmental assessment under § 25.40 of this chapter.

(iv) The applicant may, at its option, submit a complete chemistry, manufacturing, and controls section 90 to 120 days before the anticipated submission of the remainder of the application. FDA will review such early submissions as resources permit.

(v) The applicant shall include a statement certifying that the field copy of the application has been provided to the applicant's home FDA district office.

(2) Nonclinical pharmacology and toxicology section. A section describing, with the aid of graphs and tables, animal and in vitro studies with drug, including the following:

(i) Studies of the pharmacological actions of the drug in relation to its proposed therapeutic indica-

tion and studies that otherwise define the pharmacologic properties of the drug or are pertinent to possible adverse effects.

(ii) Studies of the toxicological effects of the drug as they relate to the drug's intended clinical uses, including, as appropriate, studies assessing the drug's acute, subacute, and chronic toxicity; carcinogenicity; and studies of toxicities related to the drug's particular mode of administration or conditions of use.

(iii) Studies, as appropriate, of the effects of the drug on reproduction and on the developing fetus.

(iv) Any studies of the absorption, distribution, metabolism, and excretion of the drug in animals.

(v) For each nonclinical laboratory study subject to the good laboratory practice regulations under Part 58 a statement that it was conducted in compliance with the good laboratory practice regulations in Part 58, or, if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(3) Human pharmacokinetics and bioavailability section. A section describing the human pharmacokinetic data and human bioavailability data, or information supporting a waiver of the submission of in vivo bioavailability data under Subpart B of Part 320, including the following:

(i) A description of each of the bioavailability and pharmacokinetic studies of the drug in humans performed by or on behalf of the applicant that includes a description of the analytical procedures and statistical methods used in each study and a

statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in Part 50.

(ii) If the application describes in the chemistry, manufacturing, and controls section tests, analytical procedures, and acceptance criteria needed to assure the bioavailability of the drug product or drug substance, or both, a statement in this section of the rationale for establishing the tests, analytical procedures, and acceptance criteria, including data and information supporting the rationale.

(iii) A summarizing discussion and analysis of the pharmacokinetics and metabolism of the active ingredients and the bioavailability or bioequivalence, or both, of the drug product.

(4) Microbiology section. If the drug is an anti-infective drug, a section describing the microbiology data, including the following:

(i) A description of the biochemical basis of the drug's action on microbial physiology.

(ii) A description of the antimicrobial spectra of the drug, including results of in vitro preclinical studies to demonstrate concentrations of the drug required for effective use.

(iii) A description of any known mechanisms of resistance to the drug, including results of any known epidemiologic studies to demonstrate prevalence of resistance factors.

(iv) A description of clinical microbiology laboratory procedures (for example, in vitro sensitivity discs) needed for effective use of the drug.

(5) Clinical data section. A section describing the clinical investigations of the drug, including the following:

(i) A description and analysis of each clinical pharmacology study of the drug, including a brief comparison of the results of the human studies with the animal pharmacology and toxicology data.

(ii) A description and analysis of each controlled clinical study pertinent to a proposed use of the drug, including the protocol and a description of the statistical analyses used to evaluate the study. If the study report is an interim analysis, this is to be noted and a projected completion date provided. Controlled clinical studies that have not been analyzed in detail for any reason (e.g., because they have been discontinued or are incomplete) are to be included in this section, including a copy of the protocol and a brief description of the results and status of the study.

(iii) A description of each uncontrolled clinical study, a summary of the results, and a brief statement explaining why the study is classified as uncontrolled.

(iv) A description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from clinical investigations, including controlled and uncontrolled studies of

uses of the drug other than those proposed in the application, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

(v) An integrated summary of the data demonstrating substantial evidence of effectiveness for the claimed indications. Evidence is also required to support the dosage and administration section of the labeling, including support for the dosage and dose interval recommended. The effectiveness data shall be presented by gender, age, and racial subgroups and shall identify any modifications of dose or dose interval needed for specific subgroups. Effectiveness data from other subgroups of the population of patients treated, when appropriate, such as patients with renal failure or patients with different levels of severity of the disease, also shall be presented.

(vi) A summary and updates of safety information, as follows:

(a) The applicant shall submit an integrated summary of all available information about the safety of the drug product, including pertinent animal data, demonstrated or potential adverse effects of the drug, clinically significant drug/drug interactions, and other safety considerations, such as data from epidemiological studies of related drugs. The safety data shall be presented by gender, age, and racial subgroups. When appropriate, safety data from other subgroups of the population of patients treated also shall be presented, such as for patients with renal failure or patients with different levels of severity of the disease. A description of any statistical analyses per-

formed in analyzing safety data should also be included, unless already included under paragraph (d)(5)(ii) of this section.

(b) The applicant shall, under section 505(i) of the act, update periodically its pending application with new safety information learned about the drug that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling and, if applicable, any Medication Guide required under part 208 of this chapter. These "safety update reports" are required to include the same kinds of information (from clinical studies, animal studies, and other sources) and are required to be submitted in the same format as the integrated summary in paragraph (d)(5)(vi)(a) of this section. In addition, the reports are required to include the case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event (unless this requirement is waived). The applicant shall submit these reports (1) 4 months after the initial submission; (2) following receipt of an approvable letter; and (3) at other times as requested by FDA. Prior to the submission of the first such report, applicants are encouraged to consult with FDA regarding further details on its form and content.

(vii) If the drug has a potential for abuse, a description and analysis of studies or information related to abuse of the drug, including a proposal for scheduling under the Controlled Substances Act. A description of any studies related to overdosage is

also required, including information on dialysis, antidotes, or other treatments, if known.

(viii) An integrated summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling.

(ix) A statement with respect to each clinical study involving human subjects that it either was conducted in compliance with the institutional review board regulations in part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in part 50.

(x) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(xi) If original subject records were audited or reviewed by the sponsor in the course of monitoring any clinical study to verify the accuracy of the case reports submitted to the sponsor, a list identifying each clinical study so audited or reviewed.

(6) Statistical section. A section describing the statistical evaluation of clinical data, including the following:

(i) A copy of the information submitted under paragraph (d)(5)(ii) of this section concerning the description and analysis of each controlled clinical study, and the documentation and supporting statistical analyses used in evaluating the controlled clinical studies.

(ii) A copy of the information submitted under paragraph (d)(5)(vi)(a) of this section concerning a summary of information about the safety of the drug product, and the documentation and supporting statistical analyses used in evaluating the safety information.

(7) Pediatric use section. A section describing the investigation of the drug for use in pediatric populations, including an integrated summary of the information (the clinical pharmacology studies, controlled clinical studies, or uncontrolled clinical studies, or other data or information) that is relevant to the safety and effectiveness and benefits and risks of the drug in pediatric populations for the claimed indications, a reference to the full descriptions of such studies provided under paragraphs (d)(3) and (d)(5) of this section, and information required to be submitted under § 314.55.

(e) Samples and labeling.

(1) Upon request from FDA, the applicant shall submit the samples described below to the places identified in the agency's request. FDA will generally ask applicants to submit samples directly to two or more agency laboratories that will perform all necessary tests on the samples and validate the applicant's analytical procedures.

(i) Four representative samples of the following, each sample in sufficient quantity to permit FDA to

perform three times each test described in the application to determine whether the drug substance and the drug product meet the specifications given in the application:

(a) The drug product proposed for marketing;

(b) The drug substance used in the drug product from which the samples of the drug product were taken; and

(c) Reference standards and blanks (except that reference standards recognized in an official compendium need not be submitted).

(ii) Samples of the finished market package, if requested by FDA.

(2) The applicant shall submit the following in the archival copy of the application:

(i) Three copies of the analytical procedures and related descriptive information contained in the chemistry, manufacturing, and controls section under paragraph (d)(1) of this section for the drug substance and the drug product that are necessary for FDA's laboratories to perform all necessary tests on the samples and to validate the applicant's analytical procedures. The related descriptive information includes a description of each sample; the proposed regulatory specifications for the drug; a detailed description of the procedures of analysis; supporting data for accuracy, specificity, precision and ruggedness; and complete results of the applicant's tests on each sample.

(ii) Copies of the label and all labeling for the drug product (including, if applicable, any Medication Guide required under part 208 of this chap-

ter) for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(f) Case report forms and tabulations. The archival copy of the application is required to contain the following case report tabulations and case report forms:

(1) Case report tabulations. The application is required to contain tabulations of the data from each adequate and well-controlled study under § 314.126 (Phase 2 and Phase 3 studies as described in §§ 312.21 (b) and (c) of this chapter), tabulations of the data from the earliest clinical pharmacology studies (Phase 1 studies as described in § 312.21(a) of this chapter), and tabulations of the safety data from other clinical studies. Routine submission of other patient data from uncontrolled studies is not required. The tabulations are required to include the data on each patient in each study, except that the applicant may delete those tabulations which the agency agrees, in advance, are not pertinent to a review of the drug's safety or effectiveness. Upon request, FDA will discuss with the applicant in a "pre-NDA" conference those tabulations that may be appropriate for such deletion. Barring unforeseen circumstances, tabulations agreed to be deleted at such a conference will not be requested during the conduct of FDA's review of the application. If such unforeseen circumstances do occur, any request for deleted tabulations will be made by the director of the FDA division responsible for reviewing the application, in accordance with paragraph (f)(3) of this section.

(2) Case report forms. The application is required to contain copies of individual case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event, whether believed to be drug related or not, including patients

receiving reference drugs or placebo. This requirement may be waived by FDA for specific studies if the case report forms are unnecessary for a proper review of the study.

(3) Additional data. The applicant shall submit to FDA additional case report forms and tabulations needed to conduct a proper review of the application, as requested by the director of the FDA division responsible for reviewing the application. The applicant's failure to submit information requested by FDA within 30 days after receipt of the request may result in the agency viewing any eventual submission as a major amendment under § 314.60 and extending the review period as necessary. If desired by the applicant, the FDA division director will verify in writing any request for additional data that was made orally.

(4) Applicants are invited to meet with FDA before submitting an application to discuss the presentation and format of supporting information. If the applicant and FDA agree, the applicant may submit tabulations of patient data and case report forms in a form other than hard copy, for example, on microfiche or computer tapes.

(g) Other. The following general requirements apply to the submission of information within the summary under paragraph (c) of this section and within the technical sections under paragraph (d) of this section.

(1) The applicant ordinarily is not required to resubmit information previously submitted, but may incorporate the information by reference. A reference to information submitted previously is required to identify the file by name, reference number, volume, and page number in the agency's records where the information

can be found. A reference to information submitted to the agency by a person other than the applicant is required to contain a written statement that authorizes the reference and that is signed by the person who submitted the information.

(2) The applicant shall submit an accurate and complete English translation of each part of the application that is not in English. The applicant shall submit a copy of each original literature publication for which an English translation is submitted.

(3) If an applicant who submits a new drug application under section 505(b) of the act obtains a "right of reference or use," as defined under § 314.3(b), to an investigation described in clause (A) of section 505(b)(1) of the act, the applicant shall include in its application a written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its application, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its application.

(h) Patent information. The application is required to contain the patent information described under § 314.53.

(i) Patent certification—

(1) Contents. A 505(b)(2) application is required to contain the following:

(i) Patents claiming drug, drug product, or method of use.

(A) Except as provided in paragraph (i)(2) of this section, a certification with respect to each patent issued by the United States Patent and Trademark Office that, in the opinion of the

applicant and to the best of its knowledge, claims a drug (the drug product or drug substance that is a component of the drug product) on which investigations that are relied upon by the applicant for approval of its application were conducted or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the act and § 314.53. For each such patent, the applicant shall provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

(1) That the patent information has not been submitted to FDA. The applicant shall entitle such a certification "Paragraph I Certification";

(2) That the patent has expired. The applicant shall entitle such a certification "Paragraph II Certification";

(3) The date on which the patent will expire. The applicant shall entitle such a certification "Paragraph III Certification"; or

(4) That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. The applicant shall entitle such a certification "Paragraph IV Certification". This certification shall be submitted in the following form:

I, (name of applicant), certify that Patent No. (is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of) (name of proposed drug product) for which this application is submitted.

The certification shall be accompanied by a statement that the applicant will comply with the requirements under § 314.52(a) with respect to providing a notice to each owner of the patent or their representatives and to the holder of the approved application for the drug product which is claimed by the patent or a use of which is claimed by the patent and with the requirements under § 314.52(c) with respect to the content of the notice.

(B) If the drug on which investigations that are relied upon by the applicant were conducted is itself a licensed generic drug of a patented drug first approved under section 505(b) of the act, the appropriate patent certification under this section with respect to each patent that claims the first-approved patented drug or that claims an approved use for such a drug.

(ii) No relevant patents. If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (i)(1)(i) of this section, a certification in the following form:

In the opinion and to the best knowledge of (name of applicant), there are no patents that claim the drug or drugs on which investigations that are relied upon in this application were conducted or that claim a use of such drug or drugs.

(iii) Method of use patent.

(A) If information that is submitted under section 505(b) or (c) of the act and § 314.53 is for a method of use patent, and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent, a statement explaining that the method of use patent does not claim any of the proposed indications.

(B) If the labeling of the drug product for which the applicant is seeking approval includes an indication that, according to the patent information submitted under section 505(b) or (c) of the act and § 314.53 or in the opinion of the applicant, is claimed by a use patent, the applicant shall submit an applicable certification under paragraph (i)(1)(i) of this section.

(2) Method of manufacturing patent. An applicant is not required to make a certification with respect to any patent that claims only a method of manufacturing the drug product for which the applicant is seeking approval.

(3) Licensing agreements. If a 505(b)(2) application is for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, the applicant shall submit a certification under paragraph (i)(1)(i)(A)(4) of this section ("Paragraph IV Certification") as to that patent and a statement that it has been granted a patent license. If the patent owner consents to an immediate effective date upon approval of the 505(b)(2) application, the application shall contain a written statement from the patent owner that it has a licensing agreement with the applicant and that it consents to an immediate effective date.

(4) Late submission of patent information. If a patent described in paragraph (i)(1)(i)(A) of this section is issued and the holder of the approved application for the patented drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted a 505(b)(2) application that, before the submission of the patent information, contained an appropriate patent certification is not required to submit an amended certification. An applicant whose 505(b)(2) application is filed after a late submission of patent information or whose 505(b)(2) application was previously filed but did not contain an appropriate patent certification at the time of the patent submission shall submit a certification under paragraph (i)(1)(i) or (i)(1)(ii) of this section or a statement under paragraph (i)(1)(iii) of this section as to that patent.

(5) Disputed patent information. If an applicant disputes the accuracy or relevance of patent information submitted to FDA, the applicant may seek a confirmation of the correctness of the patent information in accordance with the procedures under § 314.53(f). Unless the patent information is withdrawn or changed, the applicant must submit an appropriate certification for each relevant patent.

(6) Amended certifications. A certification submitted under paragraphs (i)(1)(i) through (i)(1)(iii) of this section may be amended at any time before the effective date of the approval of the application. An applicant shall submit an amended certification as an amendment to a pending application or by letter to an approved application. If an applicant with a pending application voluntarily makes a patent certification for an untimely filed patent, the applicant may withdraw the patent certification for the untimely filed patent. Once an amend-

ment or letter for the change in certification has been submitted, the application will no longer be considered to be one containing the prior certification.

(i) After finding of infringement. An applicant who has submitted a certification under paragraph (i)(1)(i)(A)(4) of this section and is sued for patent infringement within 45 days of the receipt of notice sent under § 314.52 shall amend the certification if a final judgment in the action is entered finding the patent to be infringed unless the final judgment also finds the patent to be invalid. In the amended certification, the applicant shall certify under paragraph (i)(1)(i)(A)(3) of this section that the patent will expire on a specific date.

(ii) After removal of a patent from the list. If a patent is removed from the list, any applicant with a pending application (including a tentatively approved application with a delayed effective date) who has made a certification with respect to such patent shall amend its certification. The applicant shall certify under paragraph (i)(1)(ii) of this section that no patents described in paragraph (i)(1)(i) of this section claim the drug or, if other relevant patents claim the drug, shall amend the certification to refer only to those relevant patents. In the amendment, the applicant shall state the reason for the change in certification (that the patent is or has been removed from the list). A patent that is the subject of a lawsuit under § 314.107(c) shall not be removed from the list until FDA determines either that no delay in effective dates of approval is required under that section as a result of the lawsuit, that the patent has expired, or that any such period of delay in effective dates of approval is ended. An

applicant shall submit an amended certification as an amendment to a pending application. Once an amendment for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph (i)(1)(i)(A)(4) of this section.

(iii) Other amendments.

(A) Except as provided in paragraphs (i)(4) and (i)(6)(iii)(B) of this section, an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate.

(B) An applicant is not required to amend a submitted certification when information on an otherwise applicable patent is submitted after the effective date of approval for the 505(b)(2) application.

(j) Claimed exclusivity. A new drug product, upon approval, may be entitled to a period of marketing exclusivity under the provisions of § 314.108. If an applicant believes its drug product is entitled to a period of exclusivity, it shall submit with the new drug application prior to approval the following information:

(1) A statement that the applicant is claiming exclusivity.

(2) A reference to the appropriate paragraph under § 314.108 that supports its claim.

(3) If the applicant claims exclusivity under § 314.108(b)(2), information to show that, to the best of its knowledge or belief, a drug has not previously been approved under section 505(b) of the act containing any

active moiety in the drug for which the applicant is seeking approval.

(4) If the applicant claims exclusivity under § 314.108(b)(4) or (b)(5), the following information to show that the application contains "new clinical investigations" that are "essential to approval of the application or supplement" and were "conducted or sponsored by the applicant:"

(i) "New clinical investigations." A certification that to the best of the applicant's knowledge each of the clinical investigations included in the application meets the definition of "new clinical investigation" set forth in § 314.108(a).

(ii) "Essential to approval." A list of all published studies or publicly available reports of clinical investigations known to the applicant through a literature search that are relevant to the conditions for which the applicant is seeking approval, a certification that the applicant has thoroughly searched the scientific literature and, to the best of the applicant's knowledge, the list is complete and accurate and, in the applicant's opinion, such published studies or publicly available reports do not provide a sufficient basis for the approval of the conditions for which the applicant is seeking approval without reference to the new clinical investigation(s) in the application, and an explanation as to why the studies or reports are insufficient.

(iii) "Conducted or sponsored by." If the applicant was the sponsor named in the Form FDA-1571 for an investigational new drug application (IND) under which the new clinical investigation(s) that is essential to the approval of its application was conducted,

identification of the IND by number. If the applicant was not the sponsor of the IND under which the clinical investigation(s) was conducted, a certification that the applicant or its predecessor in interest provided substantial support for the clinical investigation(s) that is essential to the approval of its application, and information supporting the certification. To demonstrate "substantial support," an applicant must either provide a certified statement from a certified public accountant that the applicant provided 50 percent or more of the cost of conducting the study or provide an explanation of why FDA should consider the applicant to have conducted or sponsored the study if the applicant's financial contribution to the study is less than 50 percent or the applicant did not sponsor the investigational new drug. A predecessor in interest is an entity, e.g., a corporation, that the applicant has taken over, merged with, or purchased, or from which the applicant has purchased all rights to the drug. Purchase of nonexclusive rights to a clinical investigation after it is completed is not sufficient to satisfy this definition.

(k) Financial certification or disclosure statement. The application shall contain a financial certification or disclosure statement or both as required by part 54 of this chapter.

(l) Format of an original application. (1) Archival copy. The applicant must submit a complete archival copy of the application that contains the information required under paragraphs (a) through (f) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular

technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. Except as required by paragraph (l)(1)(i) of this section, applicants may submit the archival copy on paper or in electronic format provided that electronic submissions are made in accordance with part 11 of this chapter.

(i) Labeling. The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in electronic format as described in paragraph (l)(5) of this section. This requirement is in addition to the requirements of paragraph (e)(2)(ii) of this section that copies of the formatted label and all labeling be submitted. Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(ii) [Reserved]

(2) Review copy. The applicant must submit a review copy of the application. Each of the technical sections, described in paragraphs (d)(1) through (d)(6) of this section, in the review copy is required to be separately bound with a copy of the application form required under paragraph (a) of this section and a copy of the summary required under paragraph (c) of this section.

(3) Field copy. The applicant must submit a field copy of the application that contains the technical section described in paragraph (d)(1) of this section, a copy of the application form required under paragraph (a) of this

section, a copy of the summary required under paragraph (c) of this section, and a certification that the field copy is a true copy of the technical section described in paragraph (d)(1) of this section contained in the archival and review copies of the application.

(4) Binding folders. The applicant may obtain from FDA sufficient folders to bind the archival, the review, and the field copies of the application.

(5) Electronic format submissions. Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

21 C.F.R. § 314.80. Postmarketing reporting of adverse drug experiences

(a) Definitions. The following definitions of terms apply to this section:

Adverse drug experience. Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

Disability. A substantial disruption of a person's ability to conduct normal life functions.

Life-threatening adverse drug experience. Any adverse drug experience that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse drug experience as it occurred, i.e., it does not include an adverse drug experience that, had it occurred in a more severe form, might have caused death.

Serious adverse drug experience. Any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/ incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one

of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Unexpected adverse drug experience. Any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents. "Unexpected," as used in this definition, refers to an adverse drug experience that has not been previously observed (i.e., included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

(b) Review of adverse drug experiences. Each applicant having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application, shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific

papers. Applicants are not required to resubmit to FDA adverse drug experience reports forwarded to the applicant by FDA; however, applicants must submit all followup information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.

(c) Reporting requirements. The applicant shall report to FDA adverse drug experience information, as described in this section. The applicant shall submit two copies of each report described in this section to the Central Document Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. FDA may waive the requirement for the second copy in appropriate instances.

(1) (i) Postmarketing 15-day "Alert reports". The applicant shall report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the applicant.

(ii) Postmarketing 15-day "Alert reports"—followup. The applicant shall promptly investigate all adverse drug experiences that are the subject of these postmarketing 15-day Alert reports and shall submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. Postmarketing 15-day Alert reports and followups to them shall be submitted under separate cover.

(iii) Submission of reports. The requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section, concerning the submission of postmarketing 15-day Alert reports, shall also apply to any person other than the applicant (nonapplicant) whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor. To avoid unnecessary duplication in the submission to FDA of reports required by paragraphs (c)(1)(i) and (c)(1)(ii) of this section, obligations of a nonapplicant may be met by submission of all reports of serious adverse drug experiences to the applicant. If a nonapplicant elects to submit adverse drug experience reports to the applicant rather than to FDA, the nonapplicant shall submit each report to the applicant within 5 calendar days of receipt of the report by the nonapplicant, and the applicant shall then comply with the requirements of this section. Under this circumstance, the nonapplicant shall maintain a record of this action which shall include:

(A) A copy of each adverse drug experience report;

(B) The date the report was received by the nonapplicant;

(C) The date the report was submitted to the applicant; and

(D) The name and address of the applicant.

(iv) Report identification. Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., "15-day Alert report," or "15-day Alert report-followup."

(2) Periodic adverse drug experience reports.

(i) The applicant shall report each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals. The applicant shall submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of approval of the application) and each annual report within 60 days of the anniversary date of approval of the application. Upon written notice, FDA may extend or reestablish the requirement that an applicant submit quarterly reports, or require that the applicant submit reports under this section at different times than those stated. For example, the agency may reestablish a quarterly reporting requirement following the approval of a major supplement. Followup information to adverse drug experiences submitted in a periodic report may be submitted in the next periodic report.

(ii) Each periodic report is required to contain: (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval (all 15-day Alert reports being appropriately referenced by the applicant's patient identification number, adverse reaction term(s), and date of submission to FDA); (b) a FDA Form 3500A (Adverse Reaction Report) for each adverse drug experience not reported under paragraph (c)(1)(i) of this section (with an index consisting of a line listing of the applicant's patient identification number and adverse reaction term(s)); and (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

(iii) Periodic reporting, except for information regarding 15-day Alert reports, does not apply to adverse drug experience information obtained from postmarketing studies (whether or not conducted under an investigational new drug application), from reports in the scientific literature, and from foreign marketing experience.

(d) Scientific literature.

(1) A 15-day Alert report based on information from the scientific literature is required to be accompanied by a copy of the published article. The 15-day reporting requirements in paragraph (c)(1)(i) of this section (i.e., serious, unexpected adverse drug experiences) apply only to reports found in scientific and medical journals either as case reports or as the result of a formal clinical trial.

(2) As with all reports submitted under paragraph (c)(1)(i) of this section, reports based on the scientific literature shall be submitted on FDA Form 3500A or comparable format as prescribed by paragraph (f) of this section. In cases where the applicant believes that preparing the FDA Form 3500A constitutes an undue hardship, the applicant may arrange with the Division of Pharmacovigilance and Epidemiology for an acceptable alternative reporting format.

(e) Postmarketing studies.

(1) An applicant is not required to submit a 15-day Alert report under paragraph (c) of this section for an adverse drug experience obtained from a postmarketing study (whether or not conducted under an investigational new drug application) unless the applicant concludes that there is a reasonable possibility that the drug caused the adverse experience.

(2) The applicant shall separate and clearly mark reports of adverse drug experiences that occur during a postmarketing study as being distinct from those experiences that are being reported spontaneously to the applicant.

(f) Reporting FDA Form 3500.

(1) Except as provided in paragraph (f)(3) of this section, the applicant shall complete FDA Form 3500A for each report of an adverse drug experience (foreign events may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form).

(2) Each completed FDA Form 3500A should refer only to an individual patient or a single attached publication.

(3) Instead of using FDA Form 3500A an applicant may use a computer-generated FDA Form 3500A or other alternative format (e.g., a computer-generated tape or tabular listing) provided that: (i) The content of the alternative format is equivalent in all elements of information to those specified in FDA Form 3500A; and (ii) the format is agreed to in advance by MedWatch: The FDA Medical Products Reporting Program.

(4) Ten copies or fewer of FDA Form 3500A and/or a copy of the instructions for completing the form may be obtained from the Division of Pharmacovigilance and Epidemiology (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. More than 10 copies of the form may be obtained by writing to the Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

(g) Multiple reports. An applicant should not include in reports under this section any adverse drug experiences that occurred in clinical trials if they were previously submitted as part of the approved application. If a report applies to a drug for which an applicant holds more than one approved application, the applicant should submit the report to the application that was first approved. If a report refers to more than one drug marketed by an applicant, the applicant should submit the report to the application for the drug listed first in the report.

(h) Patient privacy. An applicant should not include in reports under this section the names and addresses of individual patients; instead, the applicant should assign a unique code number to each report, preferably not more than eight characters in length. The applicant should include the name of the reporter from whom the information was received. Names of patients, health care professionals, hospitals, and geographical identifiers in adverse drug experience reports are not releasable to the public under FDA's public information regulations in Part 20.

(i) Recordkeeping. The applicant shall maintain for a period of 10 years records of all adverse drug experiences known to the applicant, including raw data and any correspondence relating to adverse drug experiences.

(j) Withdrawal of approval. If an applicant fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

(k) Disclaimer. A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a

conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an adverse effect. For purposes of this provision, the term "applicant" also includes any person reporting under paragraph (c)(1)(iii) of this section.

21 C.F.R. § 314.81. Other postmarketing reports

(a) Applicability. Each applicant shall make the reports for each of its approved applications and abbreviated applications required under this section and section 505(k) of the act.

(b) Reporting requirements. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

(1) NDA—Field alert report. The applicant shall submit information of the following kinds about distributed drug products and articles to the FDA district office that is responsible for the facility involved within 3 working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: "NDA—Field Alert Report."

(i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contn, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application.

(2) Annual report. The applicant shall submit each year within 60 days of the anniversary date of U.S. approval of the application, two copies of the report to the FDA division responsible for reviewing the application. Each annual report is required to be accompanied by a completed transmittal Form FDA 2252 (Transmittal

of Periodic Reports for Drugs for Human Use), and must include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval that ends on the U.S. anniversary date. The report is required to contain in the order listed:

(i) Summary. A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study. The summary shall briefly state whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents) shall be provided, including dosage form.

(ii) Distribution data. Information about the quantity of the drug product distributed under the approved application, including that distributed to distributors. The information is required to include the National Drug Code (NDC) number, the total number of dosage units of each strength or potency distributed (e.g., 100,000/5 milligram tablets, 50,000/10 milliliter vials), and the quantities distributed for domestic use and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required.

(iii) Labeling.

(a) Currently used professional labeling, patient brochures or package inserts (if any), and a representative sample of the package labels.

(b) The content of labeling required under § 201.100(d)(3) of this chapter (i.e., the package insert or professional labeling), including all text, tables, and figures, must be submitted in electronic format. Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files). Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(c) A summary of any changes in labeling that have been made since the last report listed by date in the order in which they were implemented, or if no changes, a statement of that fact.

(iv) Chemistry, manufacturing, and controls changes.

(a) Reports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug (such as the drug's behavior or properties in relation to microorganisms, including both the

effects of the drug on microorganisms and the effects of microorganisms on the drug). These reports are only required for new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug product.

(b) A full description of the manufacturing and controls changes not requiring a supplemental application under § 314.70 (b) and (c), listed by date in the order in which they were implemented.

(v) Nonclinical laboratory studies. Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product. The applicant shall submit a copy of a published report if requested by FDA.

(vi) Clinical data.

(a) Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant. Review articles, papers describing the use of the drug product in medical practice, papers and abstracts in which the drug is used as a research tool, promotional articles, press

clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(b) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

(c) Analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population shall be included.

(vii) Status reports of postmarketing study commitments. A status report of each postmarketing study of the drug product concerning clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that is required by FDA (e.g., accelerated approval clinical benefit studies, pediatric studies) or that the applicant has committed, in writing, to conduct either at the time of approval of an application for the drug product or a supplement to an application, or after approval of the application or a supplement. For pediatric studies, the status report shall include a statement indicating whether postmarketing clinical studies in pediatric populations were required by FDA under § 201.23 of this chapter. The status of these postmarketing studies shall be reported annually until FDA notifies the applicant, in writing, that the agency concurs with the applicant's determination that the study commitment has been fulfilled or that the study is

either no longer feasible or would no longer provide useful information.

(a) Content of status report. The following information must be provided for each postmarketing study reported under this paragraph:

(1) Applicant's name.

(2) Product name. Include the approved drug product's established name and proprietary name, if any.

(3) NDA, ANDA, and supplement number.

(4) Date of U.S. approval of NDA or ANDA.

(5) Date of postmarketing study commitment.

(6) Description of postmarketing study commitment. The description must include sufficient information to uniquely describe the study. This information may include the purpose of the study, the type of study, the patient population addressed by the study and the indication(s) and dosage(s) that are to be studied.

(7) Schedule for completion and reporting of the postmarketing study commitment. The schedule should include the actual or projected dates for submission of the study protocol to FDA, completion of patient accrual or initiation of an animal study, completion of the study, submission of the final study report to FDA, and any additional milestones or submissions for

which projected dates were specified as part of the commitment. In addition, it should include a revised schedule, as appropriate. If the schedule has been previously revised, provide both the original schedule and the most recent, previously submitted revision.

(8) Current status of the postmarketing study commitment. The status of each postmarketing study should be categorized using one of the following terms that describes the study's status on the anniversary date of U.S. approval of the application or other agreed upon date:

(i) Pending. The study has not been initiated, but does not meet the criterion for delayed.

(ii) Ongoing. The study is proceeding according to or ahead of the original schedule described under paragraph (b)(2)(vii)(a)(7) of this section.

(iii) Delayed. The study is behind the original schedule described under paragraph (b)(2)(vii)(a)(7) of this section.

(iv) Terminated. The study was ended before completion but a final study report has not been submitted to FDA.

(v) Submitted. The study has been completed or terminated and a final

study report has been submitted to FDA.

(9) Explanation of the study's status. Provide a brief description of the status of the study, including the patient accrual rate (expressed by providing the number of patients or subjects enrolled to date, and the total planned enrollment), and an explanation of the study's status identified under paragraph (b)(2)(vii)(a)(8) of this section. If the study has been completed, include the date the study was completed and the date the final study report was submitted to FDA, as applicable. Provide a revised schedule, as well as the reason(s) for the revision, if the schedule under paragraph (b)(2)(vii)(a)(7) of this section has changed since the last report.

(b) Public disclosure of information. Except for the information described in this paragraph, FDA may publicly disclose any information described in paragraph (b)(2)(vii) of this section, concerning a postmarketing study, if the agency determines that the information is necessary to identify the applicant or to establish the status of the study, including the reasons, if any, for failure to conduct, complete, and report the study. Under this section, FDA will not publicly disclose trade secrets, as defined in § 20.61 of this chapter, or information, described in § 20.63 of this chapter, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(viii) Status of other postmarketing studies. A status report of any postmarketing study not included under paragraph (b)(2)(vii) of this section that is being performed by, or on behalf of, the applicant. A status report is to be included for any chemistry, manufacturing, and controls studies that the applicant has agreed to perform and for all product stability studies.

(ix) Log of outstanding regulatory business. To facilitate communications between FDA and the applicant, the report may, at the applicant's discretion, also contain a list of any open regulatory business with FDA concerning the drug product subject to the application (e.g., a list of the applicant's unanswered correspondence with the agency, a list of the agency's unanswered correspondence with the applicant).

(3) Other reporting—

(i) Advertisements and promotional labeling. The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Mailing pieces and labeling that are designed to contain samples of a drug product are required to be complete, except the sample of the drug product may be omitted. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. Form FDA-2253 may be obtained from the PHS Forms and

Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857.

(ii) Special reports. Upon written request the agency may require that the applicant submit the reports under this section at different times than those stated.

(iii) Withdrawal of approved drug product from sale.

(a) The applicant shall submit on Form FDA 2657 (Drug Product Listing), within 15 working days of the withdrawal from sale of a drug product, the following information:

(1) The National Drug Code (NDC) number.

(2) The identity of the drug product by established name and by proprietary name.

(3) The new drug application or abbreviated application number.

(4) The date of withdrawal from sale. It is requested but not required that the reason for withdrawal of the drug product from sale be included with the information.

(b) The applicant shall submit each Form FDA-2657 to the Records Repository Team (HFD-143), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Reporting under paragraph (b)(3)(iii) of this section constitutes compliance with the requirements under § 207.30(a) of this chapter

to report "at the discretion of the registrant when the change occurs."

(c) General requirements—

(1) Multiple applications. For all reports required by this section, the applicant shall submit the information common to more than one application only to the application first approved, and shall not report separately on each application. The submission is required to identify all the applications to which the report applies.

(2) Patient identification. Applicants should not include in reports under this section the names and addresses of individual patients; instead, the applicant should code the patient names whenever possible and retain the code in the applicant's files. The applicant shall maintain sufficient patient identification information to permit FDA, by using that information alone or along with records maintained by the investigator of a study, to identify the name and address of individual patients; this will ordinarily occur only when the agency needs to investigate the reports further or when there is reason to believe that the reports do not represent actual results obtained.

(d) Withdrawal of approval. If an applicant fails to make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

21 C.F.R. § 314.105. Approval of an application and an abbreviated application

. . .

(c) FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling, and an abbreviated application after it determines that the drug meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to the statutory standards and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards. FDA makes its views on drug products and classes of drugs available through guidance documents, recommendations, and other statements of policy.

21 C.F.R. § 314.150 Withdrawal of approval of an application or abbreviated application

(a) The Food and Drug Administration will notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in §§ 310.6 and 314.151(a) of this chapter and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, if any of the following apply:

(1) The Secretary of Health and Human Services has suspended the approval of the application or abbreviated application for a new drug on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) FDA finds:

(i) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(ii) That new evidence of clinical experience, not contained in the application or not available to FDA until after the application or abbreviated application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application or abbreviated application was approved, evaluated together with the evidence available when

the application or abbreviated application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(iii) Upon the basis of new information before FDA with respect to the drug, evaluated together with the evidence available when the application or abbreviated application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126, that the drug will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(iv) That the application or abbreviated application contains any untrue statement of a material fact; or

(v) That the patent information prescribed by section 505(c) of the act was not submitted within 30 days after the receipt of written notice from FDA specifying the failure to submit such information; or

(b) FDA may notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, if the agency finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports under section 505(k) or 507(g) of the act and § 314.80, § 314.81, or § 314.98, or that the applicant has refused to permit access to, or copying or verification of, its records.

(2) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the agency.

(3) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular, and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the agency.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(5) That the applicant has failed to submit bioavailability or bioequivalence data required under part 320 of this chapter.

(6) The application or abbreviated application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other

information about the drug pertinent to an evaluation of the application or abbreviated application that is received or otherwise obtained by the applicant from any source.

(7) That any nonclinical laboratory study that is described in the application or abbreviated application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance was provided or, if it was, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(8) Any clinical investigation involving human subjects described in the application or abbreviated application, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(9) That the applicant or contract research organization that conducted a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter that is contained in the application or abbreviated application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(10) That the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the listed drug referred to in the abbreviated new drug application, except for differences approved in the abbreviated new drug application or those differences resulting from:

(i) A patent on the listed drug issued after approval of the abbreviated new drug application; or

(ii) Exclusivity accorded to the listed drug after approval of the abbreviated new drug application that do not render the drug product less safe or effective than the listed drug for any remaining, nonprotected condition(s) of use.

(c) FDA will withdraw approval of an application or abbreviated application if the applicant requests its withdrawal because the drug subject to the application or abbreviated application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section applies to the drug. FDA will consider a written request for a withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application or abbreviated application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a drug is sufficiently serious that the drug should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application or abbreviated application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the agency will not make a finding under para-

graph (b) of this section, but will withdraw approval of the application or abbreviated application in a notice published in the Federal Register that contains a brief summary of the agency's and the applicant's views of the reasons for withdrawal.

UNITED STATES DISTRICT COURT
E.D. TEXAS
SHERMAN DIVISION

No. 4:05CV84
Dec. 7, 2006

ROZLYN ACKERMANN, Individually and as a Personal Representative of Martin Lindsey Ackermann,

—v.—

WYETH PHARMACEUTICALS.

Arnold Anderson (Andy) Vickery, Vickery & Waldner, Houston, TX, for Rozlyn Ackermann, Individually and as a Personal Representative of Martin Lindsey Ackermann.

David Booth Alden, Edward J. Sebold, Mark Hermann, Jones Day, Cleveland, OH, David S. Rutkowski, Jones Day, Washington, DC, Susan E. Burnett, Michael R. Klatt, Clark Thomas & Winters, Austin, TX, for Wyeth Pharmaceuticals.

MEMORANDUM ADOPTING REPORT AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

MICHAEL H. SCHNEIDER, District Judge.

Came on for consideration the above-referenced civil action, this Court having heretofore ordered this case be referred to Magistrate Judge Don D. Bush for all pretrial purposes.

The report of the United States Magistrate Judge, which contains proposed findings of fact and recommendations for the disposition of Defendant's Motion for Summary Judgment (Docket No. 77), has been presented for consideration. The Court having made a *de novo* review of the objections raised by Plaintiff thereto, is of the opinion that the findings and conclusions of the Magistrate Judge are correct, and the objections of the Plaintiff are without merit. Therefore, the Court hereby adopts the findings and conclusions of the Magistrate Judge as the findings and conclusions of this Court. It is, therefore,

ORDERED that the Magistrate Judge's Report is **ADOPTED** as the opinion of the Court. It is further

ORDERED that Defendant's Motion for Summary Judgment is hereby the **GRANTED.**

DON D. BUSH, Magistrate Judge.

REPORT AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

Before the Court is Defendant's Motion for Summary Judgement. (Docket No. 77). The facts of the case are essentially not in dispute. On January 17, 2002, Plano

police were dispatched to the home of Martin Ackermann ("Ackermann"). Ackermann's son had called 911 notifying the dispatcher that his father had shot himself. Police encountered the son and his mother, the Plaintiff in this action, outside the house "screaming and crying." The son told police that "he (Ackermann) shot himself and there's blood everywhere." The police entered the residence and found Ackermann in an office /study area. According to reports and the autopsy results, he had shot himself in the mouth with a revolver.

Ackermann had been depressed. Mrs. Ackermann told hospital personnel a number of factors which may have played some role in his depression. She stated that she had recently been treated for breast cancer, that Ackermann's brother had died of cancer and that his mother had Alzheimer's disease. There was also information that his business had suffered since the 9-11 attacks and that he had been seeing a psychiatrist. His wife said he had been taking Selexis [sic] and she thought the medication had caused him to talk strangely. (Def.'s Mot. Summ. J., Ex. L). A toxicology exam revealed only the presence of citalopram which is marketed under the brand name of Celexa, manufactured by Forest Laboratories. (*Id.*, Ex. K). Medical reports on admission to ER also note that he was taking Celexa. (*Id.*, Ex. M).

Ackermann was treated for depression prior to the time he saw Dr. Sonn. There is no dispute that he was taking Celexa prior to the time he saw Dr. Sonn. He filled a prescription for Celexa on November 12, 2001. Celexa is a selective serotonin reuptake inhibitor ("SSRI"). He was referred to Dr. Sonn by a lawyer friend. He saw Dr. Sonn on the evening of January 4th and again on January 5th, 2002. Dr. Sonn testified that he also saw Ackermann on January 9th and January 12th, 2002. Dr. Sonn testified that he gave Ackermann a

sample pack of Effexor. Effexor is manufactured by Wyeth Pharmaceuticals ("Wyeth"). The pack contained dosage for two weeks. The sample pack Dr. Sonn gave Ackermann was labeled "Sample-Not For Sale" on both the box and the pill-blister pack inside the box. For the first week, Ackermann was to take one pill of 37.5 milligram strength. The second week, the dosage increased to 75 milligram strength. According to Mrs. Ackermann, her husband took three 37.5 milligram tablets on January 6th, 7th and 8th respectively, and then four more 75 milligram tablets on the 9th through the 12th. It does not appear he took any Effexor after January 12th. Dr. Sonn testified that he last saw Ackermann on the 12th and that Ackermann complained that the medication was affecting his "manhood." Ackermann terminated his relationship with Dr. Sonn on January 12th. It appears from Mrs. Ackermann's deposition that Ackermann resumed taking Celexa after discontinuing Effexor. She claims that Dr. Sonn put him back on Celexa. In any event, the presence of Celexa in his blood indicates that he went back on Celexa and there does not appear to be much dispute on this issue.

When Dr. Sonn treated Ackermann, he (a) reviewed the Effexor package insert that was reproduced in the Physicians' Desk Reference (Def.'s Mot. Summ. J., Ex. C, Sonn. Dep. at 42:11-43:25, Dec. 19, 2005); (b) was aware that depressed patients have a heightened risk of suicide (*Id.* at 18:16-19, 28:4-12, 28:15-19); (c) was aware of the need to monitor depressed patients for suicidal thinking and monitored Ackermann for that purpose (*Id.* at 32:10-14, 34:3-5); (d) was aware of claims that Effexor might be causally related to suicide or suicidality and considered those risks in treating Ackermann (*Id.* at 38:9-18); (e) chose (and still chooses) not to discuss suicide-related risks with patients directly

because mentioning suicide might prompt suicidal thinking or cause patients to stop treatment (*Id.* at 1117:20-22, 119:20- 120:20, 121:21-25); (f) was aware that some Effexor patients attempt suicide, have suicidal ideation, and experience agitation or akathisia, but saw no signs of those in Ackermann (*Id.* at 41:2-8, 44:1-7, 44:12, 45:7-15, 48:6-9, 98:23-25, 133:12-14, 136:14-18; 150:18-22); (g) was aware that patients who have taken large doses of Effexor for substantial periods of time may need to be tapered off Effexor (*Id.* at 25:20-25, 147:1-3); and (h) saw no need to taper Ackermann off Effexor because he had taken only a low dose for a short period of time (*Id.* at 145:17-146:2, 148:4-10).

Despite his current knowledge of Ackermann's suicide and changes to antidepressant warnings made since January 2002, Dr. Sonn (a) still believes Effexor's January 2002 package insert gave adequate warnings about the drug's suicide-related risks (*Id.* at 53:22-54:?, 116:5-8); (b) would prescribe Effexor to Ackermann today (*Id.* at 157:10-13); (c) would take the same approach to warnings that he did with the Ackermanns in January 2002 (*Id.* at 127:16-19; 130:5-8; 157:2-7; 187:11-19; 188:7-20); and (d) believes Effexor's benefits outweigh its risks (*Id.* at 20:23-21:2).

Standard

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). Disputes about material facts are genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The evidence and inferences from the summary judgment record must be viewed in the light most favorable to the nonmovant. *Minter v. Great Am. Ins. Co.*, 423 F.3d 460, 465 (5th Cir.2005); *See also McNeil v. Wyeth*, 462 F.3d 364 (5th Cir.2006).

Fraud and Misrepresentation

In her complaint, Plaintiff sued for fraud and misrepresentation. In her amended response, Plaintiff has abandoned these theories of recovery. Therefore, Defendant is entitled to judgement on these claims.

Breach of Warranties and DTPA

In her complaint, Plaintiff also sues for breach of express and implied warranties. She never specifies what implied warranties nor what express warranty she is referring to in her complaint. Her response to Defendant's Motion for Summary Judgement on this ground is no model of clarity. The gist of Plaintiff's complaint is that not enough was disclosed, not that there was a disclosure that somehow was breached. She claims that implied warranties were breached without much specification. Plaintiff "bootstraps" her breach of warranty claim into a Deceptive Trade Practices Act ("DTPA") claim under Tex. Bus. Comm.Code section 17.50(a). Wyeth argues that there can be no breach of warranty in that Ackermann never purchased Effexor from Wyeth nor did he do so from Dr. Sonn. In fact, Wyeth argues that Dr. Sonn merely gave Ackermann free samples. Plaintiff argues that he can be a consumer under the DTPA since he "purchased or acquired" medical services from Dr. Sonn. Privity is not required to enforce an

express warranty under the DTPA. *U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194 (Tex.App.-Houston [1st Dist.] 2003, *pet. denied*). Privity is not required in order to be a consumer under the DTPA. *Amstadt v. U.S. Brass Corp.*, 919 S.W.2d 644, 649 (Tex.1996); *Cameron v. Terrell & Garrett, Inc.*, 618 S.W.2d 535, 540-41 (Tex.1981). Yet, the DTPA does not define or create any warranties. *Parkway Co. v. Woodruff*, 901 S.W.2d 434, 438 (Tex.1995). Warranties actionable under the DTPA, both express and implied, must be first recognized by common law or created by statute. *Id.*

Sections 2.313, 2.314 and 2.315 of the Tex. Bus. Comm.Code contemplate a sale: ". . . any affirmation of fact or promise made by the seller to the buyer," § 2.313(a)(1); ". . . a warranty that the goods shall be merchantable is implied in a contract for their sale," § 2.314; and "where the seller at the time of contracting has reason to know any particular purpose for which the goods are required . . ." § 2.315. A sale consists in the passing of title from the seller to the buyer for a price. *Id.* at § 2.106. A buyer means a person who buys or contracts to buy goods. *Id.* at § 2.103(a)(1). A seller means a person who sells or contracts to sell goods. The definition of goods by implication excludes services. *Id.* at § 2.105. A contract refers to a *sale* of goods. Bottom line, under strict statutory interpretation, there must be an underlying sale to trigger the applicability of the Uniform Commercial Code ("UCC").

In any event, the Court agrees with the Defendant that no express warranty was identified, but more importantly, there has been no showing that Ackermann relied on any express warranty. In Texas, reliance is not only relevant to, but an element of proof, for sustaining a claim for breach of an express warranty. *See generally, Compaq Computer Corp. v. Lapray*, 135 S.W.3d 657

(Tex.2004). Here, there is absolutely *no evidence* that Ackermann relied on any affirmation by Wyeth. Summary Judgment is appropriate for Wyeth on Plaintiff's claim for breach of express warranty without further discussion or analysis. Any claim for a DTPA violation based on breach of an express warranty is also foreclosed. As to a breach of an implied warranty of merchantability under Tex. Bus. Comm.Code section 2.314, no privity of contract is required in a suit for personal injuries, i.e. whether analyzed as horizontal or vertical privity. *See Garcia v. Tex. Instruments,* 610 S.W.2d 456 (Tex.1980). Under the Texas Supreme Court's reasoning in *Garcia,* a person who has not purchased a product can still sue for breach of an implied warranty. However, Wyeth argues that there must still be an underlying sale of goods to create a nexus of liability and trigger applicability of the UCC. In this case, there is no disagreement that the Effexor given to Ackermann was a free sample furnished by Wyeth. Plaintiff argues that there was an "expectation of a sale" or that Ackermann purchased services, and therefore goods, from Dr. Sonn. There is no evidence that Ackermann ever purchased Effexor from Dr. Sonn. No bill has been produced which references any such transaction. In fact, the sample pack notes that the drugs are merely samples and *not for sale.* (Def.'s Mot. Summ. J., Ex. I). Under Texas law, the UCC only applies to transactions involving the sale of goods. Tex. Bus. Comm.Code § 2.102; *Loyd v. ECO Res., Inc.,* 956 S .W.2d 110 (Tex.App.-Houston [14th Dist.] 1997, *no pet.*). Mere promotion of the drugs is not the same as a sale of the drugs. *Yurcic v. Purdue Pharm., L.P.,* 343 F. Supp 2d 386 (M.D.Pa.2004). Moreover, to demonstrate a breach of an implied warranty of merchantability, a plaintiff must establish that the product has a defect which renders it unfit for its ordinary purpose. *Gen.*

Motors v. Garza, 179 S.W.3d 76 (Tex.App.-San Antonio 2005, *no pet.*). To recover damages for breach of an implied warranty of merchantability, a plaintiff must prove there was some defect in the product, that is to say, a condition of the goods that renders them unfit for the ordinary purpose for which they are used because of a lack of something necessary for adequacy. *Otis Spunkmeyer, Inc. v. Blakely*, 30 S.W.3d 678 (Tex.App.-Dallas 2000, *no pet.*). There is no evidence that Effexor is not fit for the ordinary purpose for which it is used, treating depression and general anxiety order. The gravamen of Plaintiff's complaint is that a drug which is normally fit for most patients reacts in a certain way with a small group of patients and therefore increases the risk of suicide. The fact that drugs such as Effexor may cause different reactions in a small group of patients is not tantamount to a holding that the drug is somehow inadequate. Notwithstanding the fact that there was no underlying sale, the Court agrees that to maintain the claim for breach of warranty, notice was required. Tex. Bus. Comm.Code § 2.607(c)(1); *Ibarra v. Nat'l Const. Rentals, Inc.*, 199 S.W.3d 32 (Tex.App.-San Antonio 2006, *no pet.*). Plaintiffs failed to give the requisite notice or to specify why such notice was excused. *U.S. Tire-Tec, Inc.*, 110 S.W.3d at 199. Although the Supreme Court of Texas has not ruled on this specific point, the official comment to section 2.607(c)(1) states *inter alia* that a plaintiff who is a mere beneficiary must notify the seller that an injury has occurred. *See Wilcox v. Hillcrest Mem'l Park of Dallas*, 696 S. W.2d 423 (Tex.App.-Dallas, 1985), *aff'd per curiam*, 701 S.W.2d 842, 843 (Tex.1986). One case has held that under facts similar to this case, furnishing samples of drugs is not a sale which triggers applicability of the UCC. *Allen v. Ortho Pharm. Corp.*, 387 F.Supp. 364 (S.D.Tex.1974). Moreover, sec-

tion 2.315 further contemplates that the "seller" has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods. Notwithstanding that Ackermann is not a buyer as defined by the Act, there is no showing that he was relying on Wyeth's skill or judgment. To the contrary, he was relying on the skill and judgment of Dr. Sonn. Effexor, like most drugs, is also indicated for other disorders, therefore, it could not be said that Wyeth would have reason to know of the particular purpose for which Effexor would be used. (*See* Def. Mot. Summ. J, Ex. G) (indicates that Effexor can be used to treat depression as well as General Anxiety Disorder). The Court concludes that Plaintiff may not prevail on her claims for breach of an implied warranty as well as an express warranty. For the reasons stated, the Court finds that Defendant is entitled to summary judgment on Plaintiff's claims under the DTPA, as well as breach of express and implied warranties.

Does the Learned Intermediary Doctrine Bar Plaintiff's Relief?

In prescription drug product liability cases, it is reasonable for the manufacturer to rely on the health care provider to pass on its warnings, as the learned intermediary understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he or she stands between the drug and the ultimate consumer. *Wyeth-Ayerst Labs. Co. v. Medrano,* 28 S.W.3d 87 (Tex.App.-Texarkana 2000, *no pet.*). Texas, like most jurisdictions, has adopted section 402A of the RESTATEMENT OF TORTS for product liability claims. *Nobility Homes, Inc., v. Shivers,* 557 S.W.2d 77, 79-80

(Tex.1977). Under that section, "[i]f a product is unreasonably or inherently dangerous, a warning is required." *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.-Corpus Christi 1973) (*citing* Restatement (Second) of Torts § 402(A) (1965)). Although adequacy as to a warning is generally a question for the fact finder, *Williams v. Upjohn Co.*, 153 F.R.D 110, 114 (S.D.Tex.1994), in cases involving prescription drugs involving the learned intermediary doctrine, when a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law. *Rolen v. Burrougs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex.App.-Waco 1993); *McNeil v. Wyeth*, 462 F.3d 364 (5th Cir.2006). However, when a warning is either inadequate or misleading, the manufacturer remains liable for injuries sustained by the patient. *McNeil, supra* note 3, at 368. To recover for a failure to warn under this doctrine, Plaintiff must show (1) a defective (or misleading) warning; and (2) the failure to warn was a producing cause of his death. *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir.1999) (citation omitted).

Was the Warning Defective?

Even though the condition or contraindication is mentioned, if the label is misleading as to the risk level for the developing the condition, the warning is defective. *See McNeil, supra.* Plaintiff complains that labeling should have warned about the increased risk of suicide particularly during the early phases of therapy and a need for a wash out period when switching from one SSRI drug to another. The package insert for Effexor notes that "the possibility of a suicide attempt is inherent in depression" and advises close supervision. This is the only mention of a "risk of suicide" contained in the

insert. Defendant relies on the lower court's ruling in *McNeil* for the support of its position that the mere mention of risk suffices. However, the Fifth Circuit has expressly ruled otherwise. Here Plaintiff argues that there should have been some disclosure that for a small subset of patients, suicidal ideation is a risk of taking Effexor. If preemption does not apply, then a fact issue as to the first prong of Plaintiff's *state law* claim on failure to warn exists.

If warnings were inadequate, was such inadequacy a producing cause of Ackermann's death?

Is there a fact issue as to causation? Ackermann took a low dosage of Effexor for a very short period of time, a week or less. The toxicology reports indicate no Effexor (venalafaine) in the post mortem blood sample. The only drug noted is 50 micrograms of citalopram (Celexis) which is consistent with a therapeutic application of the drug. (Def.'s Mot. Summ. J., Ex. J, Barbieri Dep. 9:2-5, June 13, 2006). There is also evidence that Ackermann told one of his treating doctors on the date of his suicide that he was not suicidal. His wife commented to medical personnel that he was on Celexa and had been acting strangely while taking *it*. The package insert does not recommend a wash out period when the drug has been taken for a week or less and Dr. Sonn indicates that no wash out period is indicated for such a low dosage.

There is a dearth of evidence linking Effexor to Ackermann's suicide. The testimony of Dr. Sonn indicates that in spite of the lack of a specific warning as advocated by the Plaintiff, he knew at the time he treated Ackermann that there was some discussion concerning antidepressants having a causative effect in regard to

suicide and that is a risk he considered in prescribing the drug. (Sonn Dep. 38: 1-18). He was also aware that in some patients taking Effexor and other antidepressants attempted suicide and had suicide ideation. (Sonn Dep. 44: 1-7; 45:7-15). Plaintiff claims there is nothing to indicate that Dr. Sonn was then or is now aware what a "legally adequate" warning from Wyeth would have told him. Plaintiff contends that Dr. Sonn did not know at the relevant time *all* the information which would have been included in a proper warning. *See Garside v. Osco Drug, Inc.*, 976 F.2d 77 (1st Cir.1992). Plaintiff argues that this is a case of no warning as opposed to an inadequate warning. Dr. Sonn's supplemental unchallenged affidavit unequivocally states that had the warning been included as advocated by the Plaintiff, nothing would have changed his decision to give Ackermann Effexor. (Declaration of Dr. Sonn). Under Texas law, a plaintiff who complains "that a prescription drug warning is inadequate must also show that the alleged inadeqaucy caused her doctor to prescribe the drug for her." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir.1999); *accord Stewart v. Janssen Pharm.*, 780 S.W.2d 910, 912 (Tex.App.-El Paso 1989). In other words, a plaintiff must show not only that a warning was inadequate, but that it was a "producing cause" of his injuries. *McNeil, supra* at 372. The doctrine of the "learned intermediary" presupposes that the physician will act as an intermediary. This function includes discussing the cost-benefit ratio with the patient if necessary. Where the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a "producing" cause of the injury because it effectively sabotages the function of the intermediary.

Here, Dr. Sonn testified that he would not have warned Ackermann of the possibility of an increased risk of suicide, primarily because he did not want to suggest to a depressed patient that suicide was an option. (Sonn Dep. 52, 117, 118, 121, 123). Dr. Sonn states he was adequately warned of the risks of Effexor. (Sonn Dep. 54). He stated that he did warn Ackermann about the possible side effect of agitation. He stated that he relied on the label as well as his own experience and knowledge when he prescribed Effexor. He testified that even in light of the new black box warnings on Effexor, he would not approach his warnings any different today. (Sonn Dep. 129, 130).

As previously noted, Dr. Sonn was aware of the fact that suicide attempts had been seen on patients taking Effexor. (Sonn Dep. 44). He was also aware that patients who had taken Effexor had been reported to have suicidal ideations. (Sonn Dep. 45). He was also aware that agitation was a possible side effect. (Sonn Dep. 48). In his declaration, he states that had there been a warning as advocated by the Plaintiff, he would still have prescribed the drug as he did and would not have told Ackermann of warnings related to suicide. In *McNeil*, the Court stated that the treating doctor gave conflicting testimony. He testified that he would have still prescribed the drug at issue but would have warned the patient. On the other hand, he testified that he would not have prescribed the drug had the drug label indicated that use for longer than twelve weeks was contraindicated because risks are significant and the benefits of such continued use have not been demonstrated. Here, Dr. Sonn testified that he would not have warned the patient irrespective of the warning. He gave his medical and professional reason for doing so. Even if Plaintiff's wife could demonstrate that Ackermann would not have taken the drug if

there was an increased risk of suicide associated with a small group of patients, such is not relevant. Dr. Sonn unqualifiedly states that no matter the scope of the warning, he would never have communicated such a warning to Ackermann. Unlike *McNeil*, this is not a case where the learned intermediary fails to pass necessary information to the patient because the manufacturer has understated the degree of risk. The Court finds that Wyeth is entitled to Summary Judgment on the learned intermediary doctrine.

Tex. Civ. Prac. & Rem.Code § 82.007

Wyeth also claims it is entitled to summary judgment based on Tex. Civ. Prac. & Rem.Code Section 82.007. The relevant section reads as follows:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. § 262), as amended; or

(2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

(b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:

(1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;

(2) the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the United States Food and Drug Administration to remove the product from the market or to withdraw its approval of the product;

(3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;

(B) the product was used as recommended, promoted, or advertised; and

(C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;

(4)(A) the defendant prescribed the pharmaceutical product for an indication not approved

by the United States Food and Drug Administration;

(B) the product was used as prescribed; and

(C) the claimant's injury was causally related to the prescribed use of the product; or

(5) the defendant, before or after pre-market approval or licensing of the product, engaged in conduct that would constitute a violation of 18 U.S.C. Section 201 and that conduct caused the warnings or instructions approved for the product by the United States Food and Drug Administration to be inadequate.

Tex. Civ. Prac. & Rem.Code Section 82.007 (2003).

Wyeth claims that it is entitled to judgment based on this presumption statute. Subsection (a) provides that there is a rebuttable presumption that Wyeth is not liable for inadequate warnings when such warnings are approved by the FDA. Wyeth also claims that subparagraph (1) is preempted by the rules and regulations of the FDA relying on the Supreme Court's decision in *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). Wyeth contends that subparagraph (1) is preempted because it is in effect a fraud on the FDA cause of action and must be severed from section 82.007. Plaintiff claims that Wyeth did not furnish evidence of foreign suicides to the FDA and therefore cannot rely on 82.007(a). Plaintiff also argues that the statute is unconstitutional, cannot be severed, and asks the Court to declare the statute unconstitutional.

A presumption is a guide for courts in fixing the burden of producing proof. *See Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex.1993). When a presumption arises, it shifts the burden of producing evidence to the

party against whom the presumption operates. *See id.* Once evidence contradicting the presumption has been offered, the presumption disappears and is not weighed or treated as evidence. *Id.* The facts supporting the presumption remain in evidence and can support any reasonable inferences that may be drawn. *Id.* The presumption does not affect the burden of persuasion. *Id.* Statutory presumptions operate in the same manner as presumptions developed through common law. *See, e.g.*, Tex. Prop.Code Ann. § 92.109(d) (Vernon 1984); *Leskinen v. Burford*, 892 S.W.2d 135, 136 (Tex.Civ.App.-Houston [14th Dist.] 1994); *City of Garland v. Dallas Morning News*, 969 S.W.2d 548 (Tex.App.-Dallas 1998), *aff'd*, 22 S.W.3d 351 (Tex.2000). The effect of a statutory presumption is to force the party against whom it operates to produce evidence to negate the presumption. *Balawajder v. Tex. Dept. of Criminal Justice Institutional Div.*, 2006 WL 2192613, at (Tex.App.-Houston [1st Dist.] July 31, 2006, *pet. filed*). In the context of a summary judgment, the party against whom a statutory presumption operates must produce sufficient evidence for the case to proceed to trial. *Id.* The Court disagrees with Wyeth's characterization that subparagraph (1) creates a cause of action of fraud on the FDA. The statute creates no cause of action. In fact, Wyeth has pled the statute as an affirmative defense.

The Supreme Court has held that state law fraud on the FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. *Buckman*, 531 U.S. at 345. Two recent circuit court opinions have analyzed a similar state statute and reached opposite results in determining whether the statute is preempted in light of *Buckman*. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir.2004); *Desiano v. Warner-Lamberts & Co.*,

2006 WL 2846454 (2006). Suffice to say, the Court believes that the language of section 82.007(a) creates nothing more than a presumption which the Defendant is free to raise. It does not create a cause of action where none existed before. If Plaintiff comes forward with evidence that the FDA was somehow misled, Plaintiff has merely rebutted a presumption that the manufacturer is not liable. The rebuttal evidence does not establish liability. Such evidence only prevents the manufacturer from obtaining a judgment in its favor without introducing other evidence such as a doctor's testimony that even with a "defective" warning, he still would have prescribed the drug in conformity with his actions without the desired warning. Therefore, the only question is whether Plaintiff has set forth some evidence to prevent Wyeth from obtaining judgment in its favor in light of the statute. Plaintiff argues that foreign incidents were not reported to the FDA. Wyeth argues that foreign incidents need not be reported. The Court declines to recommend summary judgment based on a presumption.

RECOMMENDATION

Based upon the foregoing, it is the Court's recommendation that Wyeth's Motion for Summary Judgment be granted on all grounds except as to the claim for relief under the Tex. Civ. Prac. and Rem.Code Section 82.007.

Within ten (10) days after receipt of the magistrate judge's report, any party may serve and file written objections to the findings and recommendations of the magistrate judge. 28 U.S.C.A. § 636(b)(1)(C).

Failure to file written objections to the proposed findings and recommendations contained in this report within ten days after service shall bar an aggrieved party from

de novo review by the district court of the proposed findings and recommendations and from appellate review of factual findings accepted or adopted by the district court except on grounds of plain error or manifest injustice. *Thomas v. Arn*, 474 U.S. 140, 148 (1985); *Rodriguez v. Bowen*, 857 F.2d 275, 276-77 (5th Cir.1988).

COURT OF APPEALS OF MICHIGAN

Docket No. 267003
June 13, 2006

GERALD DURONIO, Individually and as Class Representative, on behalf of all others similarly situated,

Plaintiff-Appellant,

—v.—

MERCK & COMPANY, INC., Andrea Benjamin, Rubin Benjamin, Angel Klein, Kathy Lindsey, Steve Mogridge, and Fawaz Naja,

Defendants-Appellees.

Before: WHITBECK C.J., and ZAHRA and DONOFRIO, JJ.

[UNPUBLISHED]

PER CURIAM.

Plaintiff appeals as of right from the trial court's order granting summary disposition in favor of defendant Merck & Company, Inc. (Merck), pursuant to MCR 2.116(C)(8). Because the trial court properly determined that plaintiff's common-law fraud claim is, in substance,

a product liability action subject to the absolute defense established by MCL 600.2946(5), and because the trial court correctly determined that the exemption in MCL 445.904(1)(a) applies to plaintiff's MCPA claim, the trial court properly dismissed plaintiff's action, and we affirm.

I. Facts and Proceedings

This action arises from Merck's withdrawal of the prescription drug Vioxx from the market. Plaintiff originally filed this action against Merck and other corporate defendants in November 2004, but plaintiff only named Merck and its alleged pharmaceutical representatives defendants his second amended complaint. Plaintiff alleged that Merck disseminated information to the general public that concealed or downplayed potential cardiovascular risks and falsely implied that Vioxx provided superior pain relief to over-the-counter medications, and that Merck's pharmaceutical representatives misled prescribing physicians regarding the safety of Vioxx for their patients.

Plaintiff sought a refund of the purchase cost of Vioxx, as well as costs and related expenses for a medical consultation recommended by the federal Food and Drug Administration (FDA) and Merck in connection with Merck's voluntary withdrawal of Vioxx from the market. Plaintiff sought recovery based on common-law fraud and the Michigan Consumer Protection Act (MCPA), MCL 445.901 *et seq.* Plaintiff also sought class certification under MCR 3.501 for all Michigan residents residing in Wayne County who have "since the FDA approval of Vioxx in 1999, taken the drug and who have not suffered death, a heart attack, stroke, or other cardiovascular or personal injury or damage to property due

to Vioxx and who have already undergone and/or will undergo the single medical consultation recommended by the FDA, Merck and/or health care professionals."

The trial court dismissed the individual defendants pursuant to the parties' stipulation. The trial court adjourned any decision on plaintiff's request for class certification until after consideration of Merck's motion for summary disposition under MCR 2.116(C)(8). The court subsequently granted Merck's motion, finding that plaintiff's liability theories, in substance, constituted a product liability action as defined in MCL 600.2945(h) of the Revised Judicature Act (RJA) and, therefore, Merck was entitled to immunity from liability under MCL 600.2946(5), given that plaintiff did not plead any constitutional exception to immunity.

II. Standard of Review

We review the interpretation and application of a statute de novo as a question of law. *Health Care Ass'n Workers Compensation Fund v. Director of the Bureau of Worker's Compensation*, 265 Mich.App. 236, 243, 694 N.W.2d 761 (2005).

> The primary goal of judicial interpretation of statutes is to ascertain and give effect to the intent of the Legislature. It is presumed that the Legislature intended the plain and obvious meaning it expressed. If the terms of a statute are ambiguous, judicial construction is appropriate. The Court must apply a reasonable construction that considers the purpose of the statute and the harm it is designed to remedy. The Court must give effect to every word, clause, and sentence, presuming that each is used for a purpose. Likewise, the Court should avoid a

> statutory construction that renders any portion of the statute surplusage or nugatory. The provisions of a statute must be read within the context of the entire statute so as to produce a harmonious and consistent enactment. [*Id.* at 243-244, 694 N.W.2d 761 (citations omitted).]

A trial court's grant of summary disposition is also reviewed de novo. *Maiden v. Rozwood*, 461 Mich. 109, 118, 597 N.W.2d 817 (1999). A motion under MCR 2.116(C)(8) tests the legal sufficiency of a claim based on the pleadings alone. *Id.* at 119-120, 597 N.W.2d 817. "All well-pleaded factual allegations are accepted as true and construed in a light most favorable to the nonmovant." *Id.* at 119, 597 N.W.2d 817. The motion may be granted only if the claim is so clearly unenforceable as a matter of law that no factual development could possible justify recovery. *Id.* Although the trial court granted summary disposition under MCR 2.116(C)(8), subrule (C)(7) is the appropriate subrule to apply where a claim is barred by immunity granted by law. An appellate court may review a trial court's decision under the correct rule. *Spiek v. Dep't of Transportation*, 456 Mich. 331, 337, 572 N.W.2d 201 (1998). In reviewing a motion under subrule (C)(7), the allegations in a complaint are accepted as true, unless contradicted by proofs submitted by the parties.[1] *Maiden, supra* at 119, 597 N.W.2d 817.

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[1] Regardless of which subrule applies, the result in this case would be the same because we are presented only with a question of law to be determined solely from the pleadings.

III. Analysis

Plaintiff argues that the trial court erred in characterizing his action as a product liability action within the meaning of MCL 600.2945(h). In general, tort law has provided the source for a product liability action. See *Neibarger v. Universal Cooperatives, Inc.*, 439 Mich. 512, 486 N.W.2d 612 (1992), and *Prentis v. Yale Mfg. Co.*, 421 Mich. 670, 682-683, 365 N.W.2d 176 (1984). In the case of an individual consumer, "the remedy for products liability is not premised upon an agreement between the parties, but derives either from a duty imposed by law or from policy considerations which allocate the risk of dangerous and unsafe products to the manufacturer and seller rather than the consumer."[2] *Neibarger, supra* at 523, 486 N.W.2d 612.

As added by 1978 PA 495, MCL 600.2946 established certain evidentiary standards for a product liability action. Evidence of compliance with governmental or industry standards was admissible to determine if the standard of care was met. *Taylor v. Gate Pharmaceuticals*, 468 Mich. 1, 6, 658 N.W.2d 127 (2003). At that time, MCL 600.2945 defined a "[p]roducts liability action" as "an action based on *any* legal or equitable theory of liability brought for on or account of death *or injury to person or property* caused by or resulting from the manufacture . . . marketing, advertising, packaging, or labeling of a product or a component of a product" (emphasis added). Later, 1995 PA 161, modified the definition section to use the phrase "injury to person or

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[2] The existence of a duty is also a necessary element for a fraud claim where it is claimed that information was suppressed. See *Hord v. Environmental Research Institute of Michigan*, 463 Mich. 399, 412, 617 N.W.2d 543 (2000); *Bergen v. Baker*, 264 Mich.App. 376, 382, 691 N.W.2d 770 (2004).

damage to property." The legislature replaced the word "any" preceding "legal or equitable theory" with the word "a."

The legislature substantially revised MCL 600.2945 to include a number of definitions, but retained the "injury to person or damage to property" phrase in the definition of "product liability action ." 1995 PA 249.

> "Product liability action" means an action based on a legal or equitable theory of liability brought for the death of a person or for *injury to a person or damage to property* caused by or resulting from the production of a product. [MCL 600.2945(h) (emphasis added).]

The word "product" is defined separately as "any and all component parts to a product," MCL 600.2945(g), and "production" is defined as "manufacture, . . . warning, instructing, marketing, selling, advertising, packaging, or labeling," MCL 600.2945(i).

The legislature also substantially modified MCL 600.2946 through its adoption of 1995 PA 249. Subject to two exceptions, MCL 600.2946(5) now establishes an absolute defense for drug manufacturers and sellers in a product liability action, where the drugs complied with FDA standards and labeling. *Taylor, supra* at 6-7, 658 N.W.2d 127. Under MCL 600.2946(5), "a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . ."

Thus, plaintiff's common-law fraud claim is subject to the absolute defense established by MCL 600.2946(5) if

it falls within the definition of "product liability action" in MCL 600.2945(h). Although we must accept the factual allegations in plaintiff's second amended complaint as true for purposes of deciding this issue, *Maiden, supra* at 119, 597 N.W.2d 817, we are not bound by a party's choice of labels for its action because this would put form over substance. See *Kostyu v. Dep't of Treasury*, 170 Mich.App. 123, 130, 427 N.W.2d 566 (1988). Plaintiff's mere allegation that he is not pursuing a product liability action is not controlling.

Because plaintiff did not allege any injury to his person, the trial court could only find a legal or equitable theory falling within the scope of MCL 600.2945(h) if plaintiff's action could be characterized as one for "damage to property" caused by or resulting from the production of Vioxx. We reject Merck's claim that plaintiff failed to preserve this particular issue for appeal. The fact that an appellant did not fully brief and argue an issue in the trial court, or that it cites authority on appeal that the trial court did not consider, does not preclude the appellant from raising the issue on appeal. *Steward v. Panek*, 251 Mich.App. 546, 554, 652 N.W.2d 232 (2002). Furthermore, we may consider the issue because it presents a question of law. *Id.*

Merck attempts to equate "damage to property" with "economic loss." We are not persuaded by Merck's assertions, because had the Legislature intended this, it would have used the phrase "economic loss," which is defined in MCL 600.2945(c), in place of "damage to property" in MCL 600.2945(h). The phrase "damage to property" is not defined in the statute so we turn to dictionary definitions to determine its plain meaning, keeping in mind the context in which it is used. *Griffith v. State Farm Mut. Automobile Ins. Co.*, 472 Mich. 521, 533, 697 N.W.2d 895 (2005); *Wessels v. Garden Way,*

Inc., 263 Mich.App. 642, 649, 689 N.W.2d 526 (2004). The *Random House Webster's College Dictionary* (1997) defines "property" as "1. that which a person owns; the possession or possessions of a particular owner. 2. goods, land, etc., considered as possessions. 3. a piece of land or real estate. 4. ownership; right of possession, enjoyment or disposal, esp. of something tangible. . . ." Also instructive is 63C Am Jur 2d, Property, § 1, which broadly defines "property" as encompassing the bundle of rights associated with an object:

> As a matter of legal definition, "property" refers not to a particular material object but to the right and interest in an object. "Property" in a thing does not consist merely in its ownership or possession, but also in the lawful, unrestricted right of its use, enjoyment, and disposal. In its precise legal sense, property is nothing more than a collection of rights.
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> * * *
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> In contemporary jurisprudence, "property" refers to the various incorporeal ownership rights in a res, such as the right to possess, to enjoy the income from, to alienate, or to recover ownership from one who has improperly obtained title to the res, as well as to the actual physical object of these rights. [(Internal footnotes and citations omitted.)]

The word "damage" is defined in *Random House Webster's College Dictionary* (1997) as "injury or harm that reduces value, usefulness, etc.", while "damages" refers to "the estimated money equivalent for loss or injury sustained." In *Universal Underwriters Ins. Co. v. Kneeland*, 464 Mich. 491, 496-497, 628 N.W.2d 491 (2001), our Supreme Court indicated that "damages" could refer to any harm caused to a third-party person or property,

or losses for which there is a legal right to recovery, when finding ambiguity in a courtesy car agreement in which the renter agreed to assume all responsibility for damages while the vehicle was in his possession. In *Smolen v. Dahlmann Apartments, Ltd.*, 127 Mich.App. 108, 114-115, 338 N.W.2d 892 (1983), this Court found that the ordinary meaning of "damage" included injury to something, when construing a statutory provision providing that a renter's security deposit may only be used to reimburse the landlord for "actual damages to the rental unit. . . ." This Court determined that a rental unit that required cleaning was not damaged. *Id.* at 115, 338 N.W.2d 892.

MCL 600.2945(h) does not use the word "damages," but rather requires an "action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person *or damage to property* caused by or resulting from the production of a product." Examined in context, we reject plaintiff's claim that "damage to property" only encompasses physical damage to property. The phrase is broad enough to include both physical damage to an object and injury or harm to rights or interests associated with an object, so long as the damage is caused by or results from the production of the product. Cf. *Holtz v. Bd. of Comm'rs of Elkhart Co.*, 560 N.E.2d 645, 647 (Ind., 1990) ("damage to property" in definition of "loss" under Indiana's Tort Claims Act includes injury to property rights and interests); see also *Indiana Dep't of Transportation v. Shelly & Sands, Inc.*, 756 N.E.2d 1063, 1077 (Ind.App., 2001) (claim against state for corporate lost profits and additional costs subject to Indiana's Tort Claims Act if it sounds in tort).

The fact that the alleged injury in this case is in the form of monetary loss does not preclude application of MCL 600.2945(h). Money itself is a form of property,

Garris v. Bekiares, 315 Mich. 141, 148-149, 23 N.W.2d 239 (1946), and a consumer's expenditure of money for overvalued goods can constitute an injury to property. Cf. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 99 S.Ct. 2326, 60 L.Ed.2d 931 (1979) (in antitrust action, an injury to "property" occurred when retail purchasers purchased consumer goods artificially inflated by anti-competitive conduct).

Plaintiff asserts that he is seeking rescission for a fraudulently induced purchase contract. In light of plaintiff's failure to adequately brief any basis for a rescission remedy against Merck, we deem this issue abandoned. An appellant may not merely announce a position and leave it to this Court to discover and rationalize its basis. *Peterson Novelties, Inc. v. City of Berkley*, 259 Mich.App. 1, 14, 672 N.W.2d 351 (2003). While rescission of a contract is an appropriate remedy for fraud in the inducement, plaintiff's request for a refund of the purchase price of Vioxx is nothing more than a claim against a noncontracting party for monetary losses measured by the cost to purchase Vioxx. Further, plaintiff presented the claim as arising from misrepresentations and omissions, and denied that the alleged concealed risks of using Vioxx ever materialized for him, but it is clear that the safety and efficacy of Vioxx is essential to his monetary loss claim.

Because plaintiff brought the claim for damage to property (money) caused by or resulting from the production (marketing, selling, advertising, packaging, or labeling) of Vioxx, plaintiff's pleaded common-law fraud claim for a refund of the cost of purchasing Vioxx is, in substance, a product liability action within the meaning of MCL 600.2945(h). Assuming for purposes of our review that plaintiff's request to have Merck pay for a medical consultation is actionable in tort, plaintiff's

alleged loss of a right or interest in money to obtain a medical consultation constitutes damage to property within the meaning of MCL 600.2945(h). Any additional claim for lost income or expenses to obtain the medical consultation is merely a pecuniary loss flowing from that injury. *Citizens for Pretrial Justice v. Goldfarb,* 415 Mich. 255, 268, 327 N.W.2d 910 (1982).

The trial court properly determined that plaintiff's common-law fraud claim is, in substance, a product liability action subject to the absolute defense established by MCL 600.2946(5). Plaintiff raises an argument concerning the validity of MCL 600.2946(5), but because it is not set forth in the statement of the questions presented, plaintiff failed to preserve this argument for our consideration. MCR 7.212(C)(5); *City of Lansing v. Hartsuff,* 213 Mich.App. 338, 351, 539 N.W.2d 781 (1995). Although we are empowered to overlook plaintiff's improper presentation of this argument, *Health Care Ass'n Workers Compensation Fund, supra* at 243, 694 N.W.2d 761, we are not persuaded that the Sixth Circuit Court of Appeals improperly decided in *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (C.A.6, 2004), that the fraud-on-the-FDA exception in MCL 600.2946(5)(a) is partially preempted by federal law. Although we are not bound to follow the decision in *Garcia,* see *Abela v. Gen. Motors Corp.,* 469 Mich. 603, 607, 677 N.W.2d 325 (2004), we agree with its holding that the fraud-on-the FDA exception is preempted by federal law unless the FDA itself determines that it was defrauded. Examined in this context, plaintiff has not established that the trial court erred in granting summary disposition in favor of Merck with respect to plaintiff's claim alleging common-law fraud. In light of this decision, we decline to address the parties' remaining arguments regarding whether there are alternative grounds

for affirming the trial court's order of summary disposition with respect to the common-law fraud claim.

Next, we turn to plaintiff's Michigan Consumer Protection Act (MCPA) claim. MCL 445.901 *et seq.* Although the trial court did not decide whether plaintiff pleaded a cognizable claim under the MCPA, we will overlook this preservation requirement to consider this issue of law. *Miller v. Inglis* 223 Mich.App. 159, 168, 567 N.W.2d 253 (1997). This claim is based on the same factual allegations and seeks the same remedy as plaintiff's common-law fraud claim. Both claims rely on alleged misrepresentations related to the safety and efficacy of Vioxx. The MCPA protects Michigan's consumers by prohibiting various methods, acts, and practices in trades or commerce. *Slobin v. Henry Ford Health Care,* 469 Mich. 211, 215, 666 N.W.2d 632 (2003); *Zine v. Chrysler Corp.*, 236 Mich.App. 261, 275, 600 N.W.2d 384 (1999). The legislature intended the MCPA to provide an "enlarged remedy for consumers who are mulcted by deceptive business practices." *Dix v. American Bankers Life Assurance Co.*, 429 Mich. 410, 417, 415 N.W.2d 206 (1987). It authorizes class actions for damages by a person who suffers a loss and by the attorney general, MCL 445.910(5) and MCL 445.911(3). The MCPA's exemptions are established by MCL 445.904, and MCL 445.916 states that "[t]his act shall not affect any other cause of action which is available."

We must give a reasonable construction to a statute that considers its purpose and the harm that it is designed to remedy. *Health Care Ass'n Workers Compensation Fund, supra* at 244, 694 N.W.2d 761. The Legislature is presumed to be aware of existing statutes when enacting new laws. *Inter Cooperative Council v. Dep't of Treasury,* 257 Mich.App. 219, 227, 668 N.W.2d 181 (2003). Based on the clear and unambiguous lan-

guage of the MCPA, the MCPA does not affect a product liability action, as defined in MCL 600.2945(h), if it is available to a plaintiff. The RJA, while using broad language to define a "product liability action" as an "action based on a legal or equitable theory of liability . . ." in MCL 600.2945(h), likewise does not bar a MCPA claim. To hold otherwise would, in effect, render the ability of a person and the attorney general to pursue a class action for damages under the MCPA a nullity, where the claim is based on deceptive advertising practices for a product, because the definition of "production" in the RJA includes "advertising." MCL 600.2945(i). A court should avoid a construction that renders any portion of a statute surplusage or a nugatory. See *Health Care Ass'n Workers Compensation Fund, supra* at 244, 694 N.W.2d 761; *Inter Cooperative Council, supra* at 225, 668 N.W.2d 181.

MCL 445.904(1)(a) provides that the MCPA does not apply to "[a] transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States." The focus of this statutory provision is not the specific misconduct alleged by a plaintiff, but whether the general transaction is authorized by law. *Smith v. Globe Life Ins. Co.*, 460 Mich. 446, 464-465, 597 N.W.2d 28 (1999); see also *Newton v. Bank West*, 262 Mich.App. 434, 438-440, 686 N.W.2d 491 (2004) (holding that the MCPA exemption applies to a residential mortgage transaction made by federal savings bank under laws administered by regulatory board or its officers); *Kraft v. Detroit Entertainment, LLC*, 261 Mich.App. 534, 540-542, 683 N.W.2d 200 (2004) (MCPA exemption applies to the operation of slot machines regulated and authorized by state statute).

The Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 USC 301 *et seq.*, governs drug marketing, manufacturing, and distribution, and vests the FDA with powers to enforce regulations. *Thompson v. Western States Medical Ctr.*, 535 U.S. 357, 361, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002). The regulations implementing the FDCA are extensive and detailed, and specifically regulate prescription drug advertising. *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934 (C.A.7, 2001); 21 CFR 202.1. Because the general marketing and advertising activities underlying plaintiff's MCPA claim are authorized and regulated under laws administered by the FDA, the exemption in MCL 445.904(1)(a) applies to plaintiff's MCPA claim. The trial court properly dismissed plaintiff's MCPA claim.

In light of this holding, we do not address the parties' arguments concerning whether plaintiff sufficiently pleaded the requisite "loss" for purposes of MCL 445.911(2) and (3) to bring an individual or class action for damages.

Affirmed.

UNITED STATES DISTRICT COURT
E.D. PENNSYLVANIA

No. 04-CV-05987-LDD
Oct. 11, 2005

MARY HENDERSON,

—v.—

MERCK & CO., INC., *et al.*

James J. McHugh, Michael S. Katz, The Beasley Firm LLC, Philadelphia, PA, for Mary Henderson.

Heather Reardon Olson, Stefanie J. Fogel, Raymond M. Williams, DLA Piper Rudnick Gray Cary LLP, Joshua G. Schiller, Dechert, Philadelphia, PA, for Merck & Co., Inc., et al.

MEMORANDUM OPINION

DAVIS, J.

Presently before the Court are defendants Pfizer, Inc., Pharmacia & Upjohn LLC, and G.D. Searle, Inc.'s ("defendants") motion for judgment on the pleadings

(Doc. No. 19), plaintiff's brief in opposition to the motion (Doc. No. 23), defendants' reply brief thereto (Doc. No. 27), and plaintiff's memorandum sur-reply in opposition to plaintiff's motion for judgment on the pleadings (Doc. No. 28). For the following reasons, this Court grants defendants' motion for judgment on the pleadings.

I. Factual and Procedural History

This action arises from alleged injuries suffered by plaintiff Mary Henderson ("plaintiff"), a resident of Michigan, from the ingestion of two prescription drugs: Bextra and Vioxx. (*See* Compl., at ¶¶ 46-50, 73-77). Plaintiff filed a complaint against defendants on December 22, 2004. (*Id.*, at ¶ 4). On April 12, 2005, the Judicial Panel on Miltidistrict Litigation entered a Conditional Transfer Order, which transferred plaintiff's Vioxx claims to the Eastern District of Louisiana. Plaintiff's Bextra-related claims remain in this forum.

The Food and Drug Administration ("FDA") approved Bextra on November 16, 2001. (*See* FDA Approval Package, attached as Ex. A to Def. Br.). Plaintiff's complaint alleges that defendant G.D. Searle, Inc. ("Searle") and defendant Pharmacia & Upjohn LLC ("Pharmacia") were initially responsible for testing, developing, manufacturing, distributing, licensing, labeling, and marketing Bextra. (*Id.*, at ¶¶ 29-30, 22-26). On April 26, 2003, defendant Pfizer, Inc. ("Pfizer") allegedly acquired the assets and liabilities of Pharmacia and Searle, continuing the business of testing, developing, manufacturing, distributing, licensing, labeling, and marketing Bextra. (*Id.*, at ¶¶ 38-39).

Plaintiff alleges that she was prescribed and began taking Bextra in 2002, and that the continued consumption of Bextra caused severe injuries, including blood

clots on December 23, 2002 and a heart attack in March 2003. (*See* Compl., at ¶¶ 67-72). Plaintiff's complaint alleges seven theories of liability against defendants: (i) negligence; (ii) products liability-defective design; (iii) products liability-failure to warn; (iv) breach of express warranty; (v) fraudulent misrepresentation; (vi) fraud; and (vii) negligent misrepresentation. Each theory pertains to the allegedly unsafe manner in which Bextra was designed, developed, manufactured, distributed, marketing, promoted, labeled, or represented.

On July 21, 2005, defendants filed a motion for judgment on the pleadings. (Doc. No. 19). Plaintiff filed a response on August 5, 2003. (Doc. No. 23). Both parties filed additional briefs in support of their respective positions. (Doc. No. 27-28).

II. Judgment on the Pleadings

Rule 12(c) of the Federal Rules of Civil Procedure permits a party to move for judgment on the pleadings after the closing of all pleadings. *See* Fed.R.Civ.P. 12(c). The standard for a Rule 12(c) motion for judgment on the pleadings is similar to that of a Rule 12(b)(6) motion to dismiss. *See, e.g., Turbe v. Government of Virgin Islands*, 938 F.2d 427, 428 (3d Cir.1991). Therefore, like a Rule 12(b)(6) motion, a Rule 12(c) motion may be granted only when it clearly appears that the opposing party can prove no set of facts in support of the claim which would entitle her to relief. *See Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Robb v. City of Philadelphia*, 733 F.2d 286, 290 (3d Cir.1984). In applying this standard, this Court "must take all the well pleaded allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the pleadings, the plaintiff may be entitled to relief." *Col-*

burn v. Upper Darby Township, 838 F.2d 663, 665-66 (3d Cir.1988).

A. Pennsylvania's Choice-of-law Methodology

The resolution of defendants' Rule 12(c) motion requires a determination of which law applies to the various claims in plaintiff's complaint. In determining the applicable law, a court must apply the choice-of-law principles of the state in which the district court sits. *Klaxon Co. v. Stentor Electric Mfg. Co.,* 313 U.S. 487, 496, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). Under Pennsylvania's choice of law rules, a court must first determine whether a conflict exists. *See, e.g., Ghallagher v. Medical Research Consultants,* 2004 WL 2223312, at n. 15 (E.D.Pa. Oct.1, 2004). If a conflict exists, the court must then characterize the "conflict" between the proposed competing bodies of law. *See, e.g., Garcia v. Plaza Oldsmobile Ltd.,* 421 F.3d 216, 220 (3d Cir.2005). Finally, if the conflict is characterized as a true conflict, the court must analyze which state has the greater interest in the application of its law. *See, e.g., Cipolla v. Shaposka,* 439 Pa. 563, 267 A.2d 854, 855 (Pa 1970).

1. Existence of Conflict

As a threshold question, a conflict exists if the application of the proposed laws would lead to different results. *See, e.g., Pilot Air Freight Corp. v. Sandair, Inc.,* 118 F.Supp.2d 557, 561 n. 3 (E.D.Pa.2000). If the application of the proposed laws would not lead to different results, the court need only apply forum law. *Id.* ("Where the different laws do not product different results, courts presume that the law of the forum state shall apply."). If it would lead to different results, the court must characterize the type of conflict.

2. Characterization

In order to determine what type of "conflict" exists, the court must perform an "interest analysis" of the policies of the interested states and then characterize the relationship between the policies and the factual predicate of the action as a true conflict, a false conflict, or an unprovided-for case. *See, e.g., Budget Rent-A-Cary System, Inc. v. Chappell,* 407 F.3d 166, 170 (3d Cir.2005).

a. True Conflict

A true conflict exists "when the government interests of multiple jurisdictions would be impaired if their law were not applied." *Lacey v. Cessna Aircraft Co.,* 932 F.2d 170, 187 n. 15 (3d Cir.1991). If a true conflict exists, Pennsylvania's choice of law rules requires the "application of the law of the state having the most significant contacts or relationships with the particular issue." *See Chappell,* 407 F.3d at 170 (internal quotations omitted).

b. False Conflict

A false conflict exists "if only one jurisdiction's governmental interests would be impaired by the application of the other jurisdiction's law." *Lacey,* 932 F.2d at 187. In the event of a false conflict, Pennsylvania's choice of law rules require the application of the law of the only interested state. *See Chappell,* 407 F.3d at 170.

c. Unprovided For Situation

Finally, an "unprovided for" situation arises when "no jurisdiction's interests would be impaired if its laws were not applied." *Id.* An unprovided-for case triggers the law of the place of the wrong. *Id.*

3. Most Significant Contacts Analysis

If a true conflict exists, a court must apply the law of the state with the greatest interest, based upon an analysis of which state has the most significant contacts with the particular issue. *See, e.g., Garcia,* 421 F.3d at 220. In making this determination, courts look to the following contacts as outlined in § 145 of the Restatement (Second) of Conflicts: (i) the place where the injury occurred; (ii) the place where the conduct causing the injury occurred; (iii) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (iv) the place where the relationship between the parties is centered. *See, e.g., Flamer v. New Jersey Transit Bus Operations, Inc.,* 414 Pa.Super. 350, 607 A.2d 260, 264 (Pa.Super.Ct.1992); *Laconis v. Burlington County Bridge Comm'n,* 400 Pa.Super. 483, 583 A.2d 1218, 1222-23 (Pa.Super.Ct.1990). These contacts should be analyzed qualitatively, rather than quantitatively, in light of the "policies and interests underlying the particular issue before the court." *See, e.g., Norman v. Johns-Manville Corp.,* 406 Pa.Super. 103, 593 A.2d 890, 893 (Pa.Super.Ct.1991).

B. Michigan Law Applies To All Claims

Defendants contend that Pennsylvania's choice of law analysis requires application of Michigan law. (*See* Def. Br., at 7). Defendants first contend that Pennsylvania law and Michigan law conflict, as they lead to difference outcomes. (*Id.*). Defendants then argue that this conflict is a false conflict, requiring application of Michigan law, because Pennsylvania's interest in applying its own law would be unimpaired if the Court, applying Michigan law, refused to allow a Michigan citizen to recover against drug manufacturers that are not residents of

Pennsylvania. (*Id.*, at 7-8, 593 A.2d 890). Furthermore, to the extent that a true conflict exists, defendants contend that Michigan is the state with the most significant relationship with plaintiff's claims. (*Id.*).

In response, plaintiff argues that defendants have failed to address the litany of additional states with interests in applying their laws to plaintiff's claims. (*See* Pl. Br., at 7). Plaintiff then submits that no conflict exists between Michigan, Pennsylvania, New York, New Jersey, and Delaware law because the different laws would not yield different results; indeed, according to plaintiff, Michigan law does not provide immunity to drug manufacturers who receive FDA approval when this approval is based upon fraudulent representations, and Pennsylvania, New York, New Jersey, and Delaware law permit all product liability claims against drug manufacturers for the manufacture, sale, or marketing of an unsafe product. (*Id.*, at 3, 593 A.2d 890). Plaintiff argues, however, that even if application of the different laws would produce different results, a false conflict exists. According to this logic, Pennsylvania, New York, New Jersey, or Delaware law should apply because, as compared to Michigan, which lacks an interest in the imposition of its law against out-of-state drug manufacturers, such as the defendants, these states have an interest in imposing liability on in-state manufacturers of defective drugs. (*Id.*, at 4-7, 593 A.2d 890).

1. A conflict exists between Michigan law, Pennsylvania law, and the laws of New York and New Jersey.[1]

Under Pennsylvania's choice of law analysis, this court must first determine whether a conflict exists. *See, e.g., McCrossan v. Wiles,* 2004 WL 1925057, at (E.D.Pa. Aug.30, 2004). A conflict exists if the laws of the states with applicable interests yields different results. *See, e.g., Travelers Cas. and Sur. Co. v. Irex Corp.,* 2002 WL 32351176, at (E.D.Pa. May 31, 2002).

Michigan is the state of plaintiff's residence, the location where plaintiff purchased, ingested, and was prescribed Bextra, and the situs of plaintiff's injuries. (*See* Compl., at ¶¶ 4, 67-72).[2] Michigan contains a statute that immunizes drug manufacturers from civil liability in a "product liability action" for injuries related to drugs that have been approved by the FDA, unless the FDA makes an express finding of fraud or bribery on the part of a defendant in the application process. *See* Mich. Comp. Laws Ann. § 600.2946(5); *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961, 967 (6th Cir.2004) (finding § 600.2946(5)(a)-(b) unconstitutional in certain contexts). A product liability action is defined as "an action based on a legal or equitable theory of liability brought

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[1] No party seeks to apply different laws to different issues. Indeed, both plaintiff and defendants group plaintiff's claims together in determining which state law to apply, conducting a choice of law analysis as to all of plaintiff's claims collectively, rather than conducting a separate choice of law analysis as to each claim individually.

[2] Plaintiff alleges that she was a resident of Michigan at all times pertinent to this litigation. (*See* Compl., at ¶ 4). Furthermore, plaintiff fails to challenge defendant's recitation of the factual contacts between this litigation and the state of Michigan. (*See* Def. Br., at 8).

for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product." *Id.* § 600.2945(g); 11 Mich. Pl. & Pr. § 81A:3 (2d ed.2005).

Pennsylvania is the forum for this action and is a state in which all the defendants allegedly do business. (*See* Compl., at ¶¶ 8, 18, 24, 31, 40).[3] Pennsylvania does not contain a statutory scheme analogous to that of Michigan. However, the Pennsylvania Supreme Court has declared that strict liability does not lie against manufacturers or sellers of pharmaceutical drugs, reasoning that pharmaceutical drugs are "unreasonably unsafe" within the meaning of comment k to § 402A of the Restatement (Second) of Torts. *See, e.g., Parkinson v. Guidant Corp.*, 315 F.Supp.2d 741, 748 n. 6 (W.D.Pa.2004) (granting summary judgment to manufacturer of prescription medical device on strict products liability claims because Pennsylvania Supreme Court "unambiguously has held that § 402A strict liability does *not* apply in any way to prescription drugs"); *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 890-891 (Pa.1996); *Anderson v. Wyeth*, 2005 WL 1383174, at , 7 (Pa. Com. Pl. Phila. Co. June 7, 2005) (pharmaceutical drug cases under Pennsylvania law can only be based upon negligence and not strict liability). On the other hand, however, Pennsylvania law, unlike Michigan law, permits negligence claims and other forms of non-strict liability tort claims against drug manufacturers. *See Hahn*, 673 A.2d at 891 (acknowledging validity of negligence claim

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[3] Plaintiff also contends that defendant Merck is a Pennsylvania corporation. (*See* Pl. Br., at 7). However, the claims against Merck pertain only to Vioxx and have been severed and transferred to the Eastern District of Louisiana. Furthermore, plaintiff alleges in her complaint that Merck is a New Jersey corporation. (*See* Compl., at ¶ 5).

against drug manufacturer for failure to warn of dangers associated with pharmaceutical drugs); *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807, 810 (Pa.1984) (acknowledging validity of negligent marketing theory of liability against drug manufacturer).

New Jersey is the state in which Pharmacia and Searle maintain their principal places of business, and, according to plaintiff, are incorporated. (*See* Compl., at ¶¶ 21, 29). New York is the state in which Pfizer maintains its principal place of business, and, according to plaintiff, is incorporated. (*Id.*, at ¶ 37, 478 A.2d 807). These states, like Pennsylvania, lack statutes immunizing drug manufacturers from strict products liability. Unlike Pennsylvania, however, the laws of New Jersey and New York permit, in various forms, strict product liability claims against manufacturers and sellers of prescription drugs. For instance, New Jersey performs a risk-utility analysis on a case-by-case basis to determine whether strict product liability claims may be brought against manufacturers of prescription drugs, reasoning that comment k to § 402A of the Restatement (Second) of Torts does not immunize all drug manufacturers from strict liability. *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374, 441-449 (N.J.1984) ("we are of the opinion that generally the principles of strict liability are applicable to manufacturers of prescription drugs"). New York permits, at the very least, failure to warn strict product liability claims against manufacturers of prescription drugs, subject to various affirmative defenses. *See, e.g., Martin v. Hacker*, 83 N.Y.2d 1, 607 N.Y.S.2d 598, 628 N.E.2d 1308, 1311 (N.Y.1993) (permitting strict liability failure to warn claim to go forward against manufacturer of pharmaceutical drugs, subject to affirmative defense of adequate warnings); *Militrano v. Lederle Laboratories*, 3 Misc.3d 523, 769 N.Y.S.2d 839,

846-847 (N.Y.Sup.Ct.2003) (suggesting that New York Court of Appeals would bar design defect liability claim against drug manufacturer). Both states also permit non-strict liability claims against drug manufacturers. *See, e.g., Rubel v. Eli Lilly & Co.*, 681 F.Supp. 151, 153 (S.D.N.Y.1987) (describing procedural history of case in which drug manufacturer found liable under New York law for negligently failing to test product); *Feldman v. Lederle Laboratories*, 125 N.J. 117, 592 A.2d 1176, 1182-1183 (N.J.1991) (implicitly acknowledging validity of negligence, gross negligence, strict liability, and breach of implied and express warranty claims against drug manufacturer under New Jersey law); *Salva v. Blum*, 277 A.D.2d 985, 716 N.Y.S.2d 527, 528 (N.Y.App.Div.2000) (permitting negligence and strict products liability, breach of warranty, and failure to warn claims against drug manufacturer under New York law for defective manufacture, distribution, testing, and marketing of drugs).

In summary, the application of Michigan law, which bars (subject to certain exceptions) all product liability claims against manufacturers of FDA-approved drugs, of Pennsylvania law, which bars strict product liability claims against manufacturers of pharmaceutical drugs but which permits negligence and other tort theories of product liability relief against such manufacturers, and of New York and New Jersey law, which permit strict liability and non-strict liability claims against drug manufacturers, would lead to different results. A conflict between these laws therefore exists.[4]

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[4] Plaintiff also claims that Delaware has an interest in this litigation by virtue of defendants' incorporation in that state. (*See* Pl. Br., at 7-8). However, plaintiff's complaint alleges that defendants are incorporated in New York and New Jersey, as compared to Delaware. (*See* Compl., at ¶¶ 21, 29, 37); *Bryson v. Brand Insulations, Inc.*, 621

2. An actual conflict exists between Michigan law, Pennsylvania law, and New York and New Jersey law.

Because a conflict exists between Michigan law, Pennsylvania law, and the laws of New York and New Jersey, the Court now characterizes the type of conflict between these competing bodies of law. *See, e.g., Cipolla,* 267 A.2d at 855.

This Court finds that a true conflict exists between Michigan law, Pennsylvania law, and New Jersey and New York law. First, Michigan's interest would be impaired by the application of another state's law. Although plaintiff contends that Michigan "would have no interest in denying a Michigan citizen the opportunity to recover for wrongdoing [allegedly] committed by a number of out-of-state corporations," this Court disagrees. (*See* Pl. Br., at 7). Part of the rationale behind the Michigan statutory scheme was the reduction of costs of FDA-approved pharmaceutical drugs for Michigan cit-

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F.2d 556, 559 (3d Cir.1980) (court must take all well-pleaded allegations as true in deciding motion for judgment on pleadings). Furthermore, to the extent that plaintiff's allegations are factually incorrect and defendants are actually incorporated in Delaware, the Court notes that the additional evaluation of the applicability of Delaware law, which is substantially similar to that of Pennsylvania on the issues raised in this litigation, would not change the ultimate outcome of this choice-of-law analysis. *See, e.g., LeJeune,* 85 F.3d at 1071 ("Delaware law, however, does not recognize strict products liability based on the rationale that such claims are preempted by the Uniform Commercial Code."); *Cline v. Prowler Idus. of Maryland, Inc.,* 418 A.2d 968, 974-975 (Del.1980) (refusing to recognize strict products liability in all cases involving sales transactions because recognition of such a theory of liability would be an impermissible form of judicial legislation in direct conflict with Delaware legislature's adoption of the Uniform Commercial Code). Michigan would still have a greater interest than Delaware in applying its own law, for the same reasons expressed in Section II-B-3 of this opinion.

izens and the encouragement of pharmaceutical companies to do business in Michigan. *See Garcia*, 385 F.3d at 967 (in enacting § 600.2946(5), "Michigan legislature was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs"). To the extent that application of another state's law would yield a judgment against defendants, all of whom are national pharmaceutical companies who sell pharmaceutical drugs to Michigan residents, Michigan's interest in preventing the "passing-on" of the costs of pharmaceutical liability judgments onto its citizenry in the form of expensive and potentially unaffordable drug prices would be impaired. *See, e.g., LeJeune v. Bliss-Salem, Inc.*, 85 F.3d 1069, 1072 (3d Cir.1996) (state could have a host of reasons for limiting products liability, including encouraging economic activity in state and lowering costs to consumers). Moreover, M.C.L.A. § 600.2946(5) does not limit itself to intra-territorial conflicts between Michigan residents and that small sub-set of pharmaceutical companies who are incorporated, or who have a primary places of business, in Michigan. Consequently, allowing a Michigan citizen to prevail against a pharmaceutical company that does business in the state of Michigan would contradict one of the primary objectives of the statute.[5]

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[5] Michigan's interest in protecting its citizens from "pass-on" costs associated with all product liability judgments against manufacturers and sellers of FDA-approved drugs readily distinguishes this case from the Third Circuit's decision in *Lacey v. Cessna Aircraft Company*, 932 F.2d 170 (3d Cir.1991), upon which plaintiff relies. (*See* Pl. Br., at 6-7). In *Lacey*, the Third Circuit performed a preliminary choice-of-law analysis as part of a broader *forum non conveniens* determination, and suggested that Pennsylvania law, which

This Court also finds that Pennsylvania's interests would be impaired by the application of Michigan law. Although Pennsylvania does not permit strict product liability actions against drug manufacturers, Pennsylvania does permit negligence claims against such manufacturers. This jurisprudence encourages drug manufacturers who do business in Pennsylvania to exercise reasonable care to produce safe products, while recognizing that it is unfair to penalize manufacturers of inherently unsafe products, such as pharmaceutical drug companies, for the mere act of designing, manufacturing, and labeling such products. Pennsylvania has alleged that all defendants do business in Pennsylvania. (*See* Compl., at ¶¶ 24, 26-28, 32, 34-36, 40, 43-45). Consequently, although Pennsylvania's interest in deterring misconduct by drug manufacturers is weakened by virtue

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recognizes strict liability against manufacturers of defective aircraft products, rather than British Columbia law, which recognizes only negligence liability against such manufacturers, would probably apply to plaintiff's claim. *Id.* at 188. The Third Circuit reasoned that only a false conflict existed because the sole interest behind British Columbia law—"fostering industry within its borders"—would not be impaired by the application of Pennsylvania strict products liability law against a defendant that did not possess an industrial operation in British Columbia. *Id.*

Unlike the situation in *Lacey*, however, the Michigan legislature chose to eliminate all product liability actions against drug manufacturers, including negligence claims, in part to make prescription drugs available and affordable to Michigan residents. In other words, the purpose of M.C.L.A. § 600.2946(5)(a) is both to encourage industry within Michigan's borders and to protect the welfare of Michigan residents. The latter interest is clearly implicated by the factual circumstances behind plaintiff's claims, and, unlike British Columbia's interest in *Lacey*, Michigan's interest would be impaired by the application of laws that recognize the validity of either strict product or negligence theories of liability against drug manufacturers for injuries arising from the production of FDA-approved drugs.

of the facts that none of the defendants are citizens of Pennsylvania for purposes of diversity jurisdiction [6] and because the plaintiff is a resident of Michigan, Pennsylvania still retains a valid interest in deterring drug manufacturers who do business in Pennsylvania from negligently designing, marketing, and labeling prescription drugs. This interest would be impaired by the application of Michigan law.

The Court further finds that the interests of New York and New Jersey, where defendants maintain their principal places of business and are allegedly incorporated, would be impaired by the application of Michigan law. These states do not *per se* exempt drug manufacturers from strict liability, negligence, or fraud claims for injuries caused by FDA approved drugs. *See, e.g., Martin,* 607 N.Y.S.2d 598, 628 N.E.2d at 1311 (strict product liability claim lies under New York law against drug manufacturers who fail to properly prepare drug and to provide adequate warnings); *Feldman,* 479 A.2d at 449 (no *per se* public policy exception under New Jersey law for design defect and failure to warn strict product liability claims against drug manufacturers, as such manufacturers should assume liability for product that is "not fit, suitable, or safe for its intended use"). To apply Michigan law would therefore impair the interests of these states in deterring resident drug manufacturers from producing and disseminating unsafe products, regardless of where the injury takes place. *See LeJeune,* 85 F.3d at 1071 (purpose of strict product liability law is for state "to protect its citizens from defective products and to encourage manufacturers to produce safe prod-

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[6] For purposes of diversity jurisdiction, a corporation is a citizen of any state by which it has been incorporated and of any state in which the corporation has its principal place of business. *See* 28 U.S.C. § 1332(c)(1).

ucts"); *Lacey*, 932 F.2d at 188 (application of law that recognizes only negligence principles would impair competing state's interest in applying its strict products liability law to deter instate manufacturer from producing defective products).

In summary, this Court concludes that a true conflict exists between Michigan law, Pennsylvania law, and the laws of New York and New Jersey, finding that the objectives of each state's law, as made relevant through the various factual circumstances of this litigation, would be impaired by the application of the law of a different state.

3. Michigan has the most significant contacts with the litigation.

The Court now determines which state has the most significant contacts with the litigation. In making this determination, this Court must look to an array of factors: (i) the place where the injury occurred; (ii) the place where the conduct causing the injury occurred; (iii) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (iv) the place where the relationship, if any, between the parties is centered. *See* Restatement (Second) of Conflicts § 145. These contacts only become important when they relate to the "policies and interests underlying the particular issue before the court." *Cipolla*, 267 A.2d at 856. The focus of the analysis therefore must be on the qualitative, rather than the quantitative, weight of the contacts. *Id.*

Applying these factors, it is clear that Michigan has the most significant qualitative contacts with this litigation. Plaintiff is a resident of Michigan. *See, e.g., Normann v. Johns-Manville Corp.*, 406 Pa.Super. 103, 593 A.2d 890, 894-895 (Pa.Super.Ct.1991) (applying law of New York, rather than law of Pennsylvania, to product

liability claims because decedent resided in New York during time of exposure to asbestos). She purchased the drugs in Michigan, thereby making Michigan the center of the parties' relationship. Presumably, a physician located in Michigan prescribed the drugs at issue. Furthermore, plaintiff's reliance on defendant's representations concerning Bextra occurred in Michigan. Perhaps most importantly, plaintiff's injuries occurred in Michigan. *See, e.g., LeJeune,* 85 F.3d at 1072 (placing great emphasis on location of accident in product liability action in determining state with greatest interest in having its law applied); *Laconis v. Burlington County Bridge Comm'n,* 400 Pa.Super. 483, 583 A.2d 1218, 1223 (Pa.Super.Ct.1990) ("in an action for personal injuries, the law of the state where the injury occurred normally determines the rights and liabilities of the parties, unless another state, applying the contacts test, has a more significant relationship to the occurrence and parties"). Based upon these contacts, the Court finds that Michigan has a strong interest in applying its law to ensure that Michigan residents, including plaintiff, are not burdened with excessively high payments for prescription drugs, indeed, that such drugs remain financially available for all Michigan citizens, even if that means immunizing non-resident pharmaceutical companies who do business in Michigan from product-related claims brought by a Michigan resident for injuries suffered in Michigan.

In comparison, the only contact between New York and New Jersey and this litigation is defendants' residence in these states; and the only contacts between Pennsylvania and this litigation is Pennsylvania's forum status and defendants' distribution of Bextra into the Pennsylvania marketplace. The importance of these contacts is diluted by the fact that the remaining relevant

events took place in Michigan. Indeed, because plaintiff is a Michigan resident, because plaintiff purchased, was prescribed, and ingested Bextra within Michigan's borders, and because plaintiff allegedly suffered injuries in Michigan, the interests of Pennsylvania, New York, and New Jersey in applying their product liability laws to such extraterritorial conduct lose vigor. *See, e.g., Laconis,* 583 A.2d at 1223 (applying Pennsylvania law over New Jersey law when Pennsylvania was the place of Pennsylvania citizen's injury, while New Jersey's only contacts with litigation were defendant's incorporation under laws of that state and defendant's transaction of business there); *Lewis v. Bayer,* 2004 WL 1146692, at 78-79 (C.C.Pl.Phila.Co. Nov. 18, 2004) (applying law of states where class members reside, took Baycol, and suffered injuries, as compared to law of state where defendant does business, to negligence claim against drug manufacturers arising from manufacturing, labeling, marketing, and ingestion of Baycol).[7] Furthermore, the Court notes that plaintiff's failure to provide any analysis as to why the interests of Pennsylvania, New York, or New Jersey are more significant than the interests of Michigan highlights the merit in this Court's conclusion that Michigan law should apply.

In summary, the Court finds that Michigan has the greatest interest in applying its product liability laws to injuries suffered in Michigan by a Michigan resident based upon the sale, prescription, and consumption of a pharmaceutical drug in Michigan. This determination comports with the expectations of the parties and the policies of all interested states.

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[7] The strength of Pennsylvania's interest in deterring the negligence of drug manufacturers is particularly diluted because, according to plaintiff's complaint, defendants are not citizens of the Commonwealth of Pennsylvania.

B. Application of Michigan law

In determining whether plaintiff's claims may proceed under Michigan law, the Court must perform a two-part analysis. First, the Court must determine whether plaintiff's claims fall under the definition of "product liability action" within the meaning § 600.2946(5)(a), which immunizes drug manufacturers and sellers of FDA approved drugs from civil liability for physical injuries arising from the production of the drug. Second, the Court must determine whether plaintiff meets any of the exceptions to this statutory scheme.

1. Civil Immunity

Subject to various exceptions, M.C.L.A. § 600.2946(5) prohibits all "product liability actions" against a manufacturer or seller of a prescription drug if the drug was approved by the FDA and if the drug was in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller. *See* Mich. Compl. Laws Ann. § 600.2946(5). The Michigan statutory scheme defines product liability actions to include any action "based on a legal or equitable theory of liability brought for the death of a person or for injury to a person . . . caused by or resulting from the production of a product." *Id.* § 600.2945(h). Production is defined broadly to include "manufacture, construction, design, formulation, . . . warning, instructing, marketing, selling, advertising, packaging, or labeling." *Id.* § 600.2945(i).

The statutory definition of "product liability action" covers each of plaintiff's claims against defendants. First, each claim seeks damages for plaintiff's physical injuries, including blood cots and her ultimate heart attack in 2003. (*See* Compl., at ¶¶ 119, 131, 145, 153,

164, 176, 186). Second, each claim attributes these injuries to the "production of a product." *See* Mich. Comp. Laws § 600.2946(5). For instance, plaintiff's negligence, defective design, failure to warn, and breach of warranty claims are covered by this definition of "production," as these claims expressly seek damages for the manner in which Bextra was designed, manufactured, marketing, advertised, distributed, promoted, tested, and sold. (*Id.*, at ¶¶ 113, 116, 123-124, 127- 128, 135-137, 149-150). Furthermore, plaintiff's fraud, fraudulent misrepresentation, and negligent misrepresentation claims emanate from the manner in which defendants sold, advertised, and marketed Bextra to the medical community and the public at large. (*Id.*, at ¶¶ 157-158, 168-170, 180-182).[8] Consequently, unless plaintiff meets an exception to the grant of immunity in § 600.2946(5), plaintiff's claims against defendants fail as a matter of law under Michigan law.

2. Exceptions

The grant of immunity in M.C.L.A. § 600.2946(5) contains two exceptions. These exceptions apply when a seller or manufacturer: (a) intentionally withholds or misrepresents information concerning the drug to the FDA in violation of the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the drug would not have been approved if the information was submitted; or (b) makes an illegal payment to an official or employee of the FDA for the purpose of securing or

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[8] Plaintiff does not argue that, under Michigan law, only certain claims in the complaint meet the definition of "product liability action." Instead, plaintiff's sole argument as to the survival of plaintiff's claims under Michigan law concerns the applicability of the exception in § 600.2946(5)(a).

maintaining approval of the drug. *See* Mich. Com. Laws Ann. § 600.2946(5)(a)-(b).

Standing alone, the text of the statutory exceptions to M.C.L.A. § 600.2946(5) would arguably permit plaintiff's claims to survive, as plaintiff's complaint alleges that defendants falsely and fraudulently represented to the "medical community" that Bextra "had been tested and found to be safe and effective for the treatment of pain." (*See* Pl. Compl., at ¶ 157). At the very least, the possibility of the applicability of the textual exceptions to M.C.L.A. § 600.2946(5) would permit plaintiff to take additional discovery on the issue of whether defendants misrepresented material information to the FDA during the approval process.

This analysis, however, is complicated by the Sixth Circuit's recent decision in *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (6th Cir.2004). In *Garcia,* the Sixth Circuit concluded that the exceptions of § 600.2946(5)(a)-(b) are preempted by the FDCA, unless the FDA itself makes an explicit finding that a defendant engaged in bribery or fraud during the drug application process. *Id.* at 967. The Sixth Circuit, in reaching this decision, relied heavily upon the Supreme Court opinion of *Buckman Co. v. Pls. Legal Comm.,* 531 U.S. 341, 350, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). Therefore, in order to determine whether plaintiff's allegations trigger the exceptions to Michigan's product liability statute, this Court must analyze: (i) the Supreme Court's decision in *Buckman;* (ii) the Sixth Circuit's decision in *Garcia* against the backdrop of *Buckman;* and (iii) the impact of the principles announced in *Buckman* and *Garcia* on the availability of M.C.L.A. § 600.2946(5)(a) to plaintiff's claims.

a. *Buckman*

In *Buckman*, the Supreme Court declared that state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, the FDCA and its allocation of regulatory powers to the FDA. *Buckman Co.*, 531 U.S. at 348. The Court first reasoned that fraud-on-the-FDA claims would undermine the responsibility of the FDA to "police fraud" in accordance with its judgment and objectives, as established through the FDCA. *Id.* at 350. The Court then noted the practical problems in recognizing the validity of state-law fraud-on-the-FDA claims, reasoning that such claims would discourage medical device manufacturers from seeking approval of devices with potentially beneficial uses that the FDA does not regulate. *Id.* at 350-351. The Court further predicted that the threat of liability from such state-law claims would require applicants to submit a "deluge" of gratuitous information during the approval process, thereby delaying the approval process and, in turn, impeding competition among predicate devices and slowing beneficial products from reaching the marketplace. *Id.* Consequently, based upon these considerations, the Court concluded that the prospect of state law litigation in fifty states against manufacturers of medical devices would "exert an extraneous pull on the scheme established by Congress," and, thus, that such claims are preempted by the FDCA. *Id.*, at 353.

b. *Garcia*

Seizing upon the holding in *Buckman*, the Sixth Circuit recently found that the exceptions in M.C.L.A. § 600.2946(5)(a) and (b) were preempted by the FDCA. *Garcia*, 385 F.3d at 967. The *Garcia* Court rejected any difference in the potentially deleterious impact on the

FDA's statutory responsibilities between state-law fraud-on-the-FDA claims and a state-law statutory scheme that immunizes drug manufacturers unless fraud-on-the-FDA exists. *Id.* at 966. According to the *Garcia* Court, permitting such a fraud exception to M.C.L.A. § 600.2946(5) would "raise the same inter-branch-meddling concerns that animated *Buckman.*" *Id.* The exceptions to M.C.L.A. § 600.2946(5), as written, therefore conflicted with the supremacy clause.

Nonetheless, the *Garcia* Court refused to find that the exceptions to M.C.L.A. § 600.2946(5) were unconstitutional in all settings. *Id.* Specifically, the *Garcia* Court acknowledged that when the FDA itself determines that fraud or bribery has been committed during the regulatory approval process, the federalism and inter-branch intrusion concerns that motivated *Buckman* were not implicated. *Id.* The *Garcia* Court therefore interpreted M.C.L.A. § 600.2946(5) to offer blanket immunity to drug manufacturers and sellers for injury caused by a drug that had been approved by the FDA, unless the FDA itself issues findings that a party committed fraud or engaged in bribery during the regulatory approval process. *Id.* at 966-967. Because plaintiff failed to offer evidence of such FDA findings, the *Garcia* Court affirmed the district court's grant of summary judgment to the defendant drug manufacturer.

At least one other federal court has used the *Garcia* rationale to invalidate a similar pro-plaintiff exception to a state statutory scheme that provides (a form of) liability immunity to drug manufacturers under certain conditions. In *Kobar v. Novartis Corporation,* 378 F.Supp.2d 1166 (D.Ariz.2005), the United Stated District Court for the District of Arizona found that A.R.S. § 12-701(B), an exception to A.R.S. § 12-701(A), which immunizes drug manufacturers and sellers from punitive

damages in product liability suits when the FDA approved the drug that allegedly caused the harm, was impliedly preempted by provisions of the FDCA that regulate the drug approval process. *Id.* at 1168, 1174. The exception to the statutory scheme permitted a plaintiff to defeat punitive damages immunity by proving, by clear and convincing evidence, that the defendant "withheld from or misrepresented to the [Food and Drug] administration information known to be material and relevant to the harm which the plaintiff allegedly suffered." *Id.* at 1168.

The *Kobar* Court applied the principles of *Buckman* and *Garcia*. First, the Court rejected plaintiff's distinction between the federalism concerns posed by recognition of a fraud-on-the-FDA state claim and those generated by a plaintiff's burden to prove that a manufacturer withheld "material and relevant" information from the FDA before or after making the drug available for public use. *Id.* at 1172. In so doing, the *Kobar* Court found that both evidentiary burdens posed the same horizontal and vertical governmental conflicts, as state courts would be placed "in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process." *Id.* at 1173. Second, the Court noted the problematic practical consequences that could stem from upholding the exception to § 12-701(A), such as delaying the application process and the public's access to potentially revolutionary drugs, belying the FDA's capacity to police and deter fraud, and increasing the costs of pharmaceutical drugs. *Id.* at 1173-1174. Finally, like the *Garcia* Court, the *Kobar* Court concluded that § 12-701(B) was unconstitutional in all situations except when the FDA

makes a finding that is has been defrauded. *Id.* at 1174-1175.

c. Availability of Statutory Exceptions to M.C.L.A. § 600.2946(5) in Light of *Buckman* and *Garcia*

This Court follows the holdings of *Buckman* and *Garcia*, and finds that M.C.L.A. § 600.2946(5)(a) and (b) are preempted by the FDCA in most situations. The Court also finds that plaintiff's claims do not fall within any of the circumstances in which M.C.L.A. § 600.2946(5)(a) and (b) are not preempted. Indeed, plaintiff has not alleged that the FDA made a finding of fraud or that bribery was involved in the FDA approval of Bextra. Finally, because plaintiff's complaint is devoid of allegations to trigger these exceptions, discovery on this issue would be futile. Accordingly, this Court holds as a matter of law that § 600.2946(5)(a) and (b) are inapplicable to plaintiff's claims.

3. Conclusion

This Court finds that Michigan law applies to all of plaintiff's claims. This Court further finds that M.C.L.A. § 600.2946(5) requires dismissal of plaintiff's claims. Specifically, the Court finds that defendants meet the elements of immunity in M.C.L.A. § 600.2946(5) with respect to plaintiff's claims and that the exceptions to this grant of immunity, in light of *Garcia*, are inapplicable. An appropriate Order follows.

ORDER

AND NOW, this 11th day of October 2005, upon consideration of defendants Pfizer, Inc. ("Pfizer"), Pharmacia & Upjohn LLC ("Pharmacia"), and G.D. Searle,

Inc.'s ("Searle") (collectively referred to as "defendants") motion for judgment on the pleadings (Doc. No. 19), plaintiff's brief in opposition to the motion (Doc. No. 23), defendants' reply brief thereto (Doc. No. 27), and plaintiff's memorandum sur-reply in opposition to defendants' motion for judgment on the pleadings (Doc. No. 28), it is hereby ORDERED that defendants' motion (Doc. No. 19) is GRANTED. It is hereby further ORDERED that all of plaintiff's claims against defendants are dismissed; and that Pfizer, Pharmacia, and Searle are therefore dismissed as parties to this litigation.

UNITED STATES DISTRICT COURT
M.D. TENNESSEE
NASHVILLE DIVISION

No. 3:06-MD-1760
Feb. 27, 2007

In re AREDIA AND ZOMETA PRODUCTS LIABILITY LITIGATION

Adam J. Berger, Schroeter, Goldmark & Bender, Seattle, WA, Andy L. Allman, Clinton L. Kelly, Fred Dulin Kelly, Kelly, Kelly & Allman, Hendersonville, TN, Annesley H. Degaris, Cory, Watson, Crowder & Degaris, P.C., Birmingham, AL, Bart T. Valad, John Vecchione, Law Firm of Bart T. Valad, PLLC, Fairfax, VA, C. Patrick Flynn, Michael K. Radford, Flynn & Radford, Brentwood, TN, Christopher A. Seeger, Seeger Weiss LLP, Newark, NJ, Crymes G. Pittman, Joseph E. Roberts, Jr., Robert G. Germany, Pittman, Germany, Roberts & Welsh, LLP, Jackson, MS, Daniel A. Osborn, Philip J. Miller, Russel H. Beatie, Beatie & Osborn, New York, NY, Dara Lovitz, Gregory S. Spizer, Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, P.C., Philadelphia, PA, David R. Gronbach, Moynahan & Minnella, LLC, Waterbury, CT, Fred Cromwell Isaac, Foerster, Isaac & Yerkes, P.A., Michael E. Seelie, Michael E.

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Morgan, Santa Monica, CA, Lewis T. Stoneburner, Michael G. Phelan, Wallace B. Wason, Jr., Cantor Arkema, P.C., Richmond, VA, Michael T. Mullen, Peter D. Tarpey, Paul B. Episcope, LLC, Chicago, IL, Pamela J. Diedrich, Roy Lenard Mason, Mason, Cawood & Hobbs, PA, Annapolis, MD, Paul Anthony Daniels, Teague, Rotenstreich & Stanaland, Greensboro, NC, Peter H. Gunst, Astrachan, Gunst & Thomas, P.C., Baltimore, MD, Richard C. Bennett, Bennett, Johnson & Galler, Oakland, CA, Robert W. Briley, Briley Law Group, PLLC, Nashville, TN, Thomas Q. Keefe, Jr., Belleville, IL, Thomas E. Rubbert, Law Offices of Thomas E. Rubbert, Pasadena, CA, William P. Woods, Woods & Woods, LLP, Evansville, IN, Windle Turley, Law Offices Of Windle Turley, P.C., Dallas, TX, Scott J. Eldredge, Burg, Simpson, Eldredge, Hersh & Jardine, P.C., Englewood, CO, for Plaintiff. Alicia M. Wyler, Stephen E. Matasich, Day Ketterer, Ltd., Canton, OH, Andrew L. Colocotronis, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, Knoxville, TN, Catherine R. Baumer, Donald W. Fowler, Heather A. Pigman, Jeffrey A. Dickey, Joe G. Hollingsworth, Katharine R. Latimer, Robert E. Johnston, Spriggs & Hollingsworth, Washington, DC, Dan E. Labelle, Halloran & Sage, LLP, Westport, CT, Deirdre C. Gallagher, Thomas W. Hayde, Jr., Spencer, Fane, Britt & Browne, LLP, Clayton, MO, Derrick K. Watson, James A. Bruen, Farella, Braun & Martel, L.L.P., San Francisco, CA, Edward W. Gerecke, Penelope A. Dixon, Carlton Fields, P.A., Tampa, FL, Edward S. Sledge, III, Frederick G. Helmsing, Jr., McDowell, Knight, Roedder & Sledge, LLC, Mobile, AL, Eric J. Buhr, Roxanne M. Wilson, Reed Smith LLP, Los Angeles, CA, Ethan D. Stein, Gibbons, Del Deo, Dolan, Griffinger & Vecccione, New York, NY, James B. King, Keefe, King & Bowman, P.S., Spokane, WA, Jim

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MDL Clerk of Court, MDL Judicial Panel, Washington, DC, pro se.

ORDER

TODD J. CAMPBELL, United States District Judge.

This documents relates to ALL CASES.

Pending before the Court is a Report and Recommendation of the Magistrate Judge (Docket No. 293), concerning Case No. 3:06-1166, to which no Objections have been filed. The Court has reviewed the Report and Recommendation and the file. The Report and Recommendation is adopted and approved.

Accordingly, the Consolidated Motion for Remand filed by Plaintiffs Francine Scalamoni, Joseph Scalamoni, George Davis and Helen Davis in Case No. 3:06-1166 (Exhibit 7 to Docket No. 15) is GRANTED, and the causes of action of Plaintiffs Francine Scalamoni, Joseph Scalamoni, George Davis and Helen Davis are remanded to the New Jersey state court. Plaintiffs' Motion for Attorney's Fees After Improvident Removal (also Exhibit 7 to Docket No. 15 in Case No. 3:06-1166) is DENIED.

IT IS SO ORDERED.

REPORT AND RECOMMENDATION

JOE B. BROWN, United States Magistrate Judge.

Related to Case No. 3:06-cv-01166.

TO: The Honorable Todd J. Campbell

I. INTRODUCTION

Plaintiffs, Francine Scalamoni, Joseph Scalamoni, George Davis and Helen Davis (hereinafter "Plaintiffs") have filed a Consolidated Motion and Memorandum of Law for Remand and Attorney's Fees After Improvident Removal (Case No. 3:06-1166, Docket Entry 15, Exhibit 7). This Consolidated Motion was referred to the undersigned for Report and Recommendation. (Case No. 3:06-MDL-1760, Docket Entry 217).

For the reasons stated below, the Magistrate Judge recommends that the Plaintiffs' Consolidated Motion for Remand be **GRANTED** and that Plaintiffs' causes of action be **REMANDED** to New Jersey state court. Further, the Magistrate Judge recommends that Plaintiffs' request for attorneys' fees be **DENIED.**

II. BACKGROUND

Plaintiffs are residents of New Jersey. (Case No. 3:06-1166, Docket Entry 15, Exhibit 4, Page 2, ¶¶ 2-5). Defendant is a corporation incorporated in Delaware with its principal offices located in New Jersey. (Case No. 3:06-1166, Docket Entry 15, Exhibit 2, Page 2, ¶ 6). The complaint was filed on August 25, 2006, in the Superior Court of New Jersey. (Case No. 3:06-1116, Docket Entry 15, Exhibit 4). The complaint alleges that Plaintiffs' developed severe osteonecrosis of the jaw (hereinafter "ONJ") caused by their use of the drug Aredia© and/or the drug Zometa© (hereinafter "the medi-

cations"). Plaintiffs request both compensatory and punitive damages under the New Jersey Products Liability Act as well as under common law theories of strict liability, negligence, breach of warranty (express and implied) and loss of consortium. In Count IV, Plaintiffs allege that Defendant negligently failed to warn Plaintiffs and their medical providers of the risks involved in using the medications. Additionally, Plaintiffs allege that Defendant failed to meet the standard of care set by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et. seq (hereinafter "FDCA"), regarding labeling. Plaintiffs contend that the labeling lacked adequate information on the use of the drugs, failed to provide adequate warnings regarding the use of the drugs, was misleading and promotional. Further, Plaintiffs contend that Defendant's acts above constitute an adulteration and/or misbranding as defined by FDCA § 331. Specifically, paragraph 45 alleges that:

> As a result of Defendant's negligence and the violations of the statutes and regulations listed above[1], Plaintiffs suffered injuries and damages as alleged herein. As a direct and proximate result of Defendant's failure to warn, Plaintiff's have developed osteonecrosis of the jaw, are at risk of developing other diseases, and have suffered compensatory damages and are entitled to punitive damages in the amounts to be proven at trial.

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[1] In addition to 21 U.S.C. § 331, Plaintiffs allege that Defendant violated the Sherman Food, Drug and Cosmetic Law and the following federal statutes regarding the labeling issues described above: 21 C.F.R Section 201.26(a), (b) and (d), 21 C.F.R. 201.57(e) and (f)(1) and (2). (Case No. 3:06-1166, Docket Entry 15, Exhibit 4, Page 11, ¶ 42).

Defendant filed a timely petition for removal from the state court to the United States District Court of New Jersey alleging that the Court has federal question jurisdiction under 28 U.S.C. § 1331.[2] (Case No. 3:06- 1166, Docket Entry 15, Exhibit 3). To support the removal, Defendant propounded three arguments. First, citing *Grable & Sons Metal Prods., Inc. V. Darue Eng'g & Mfg,*[3] Defendant advanced that Plaintiffs' claims require resolution of substantial federal issues, even though a federal cause of action is not directly listed in the complaint, because Plaintiffs allege that the FDA-approved labeling of the medications was inadequate, false and misleading and that the medications were not adequately tested. Second, Defendant puts forth that the Court has federal question jurisdiction under the doctrine of complete preemption because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medications that any challenge to such marketing and promotion necessarily states a federal cause of action: violation of the FDCA and its implementing regulations." Third, and lastly, Defendant argues that Plaintiffs' claim for punitive damages also raises a substantial federal question because New Jersey's product liability punitive damages statute incor-

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[2] Interestingly enough, there are still several cases pending against the Defendant involving these specific medications which are currently pending in New Jersey state court. Therefore, to some extent, the argument about remand of this one case is a bit of a tempest in a teapot.

[3] 545 U.S. 308, 125 S.Ct. 2363, 2366-67, 162 L.Ed.2d 257 (2005). Additionally, Defendant cites an FDA memorandum regarding the approval of product labeling, conflicting state law claims related to the adequacy of prescription drug warnings, and preemption arguments. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed.Reg. 3922, 3934, 39935 (Jan. 24, 2006).

porates federal law by providing for a fraud-on-the-FDA prerequisite.[4]

Plaintiffs filed the instant motion to remand to the state forum on the ground that federal court lacks subject matter jurisdiction as each of the Plaintiffs' seven claims in their well pleaded complaint are based on state statutory or common law. (Case No. 3:06-1166, Docket Entry 15, Exhibit 7). Further, Plaintiffs request their attorneys' fees and costs. Shortly after filing the instant motion and subsequent response and reply, this case was transferred to this District for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. (Case No. 3:06-1166, Docket Entry 15, Exhibit 16). It appears that neither party objected to the transfer.

III. LEGAL DISCUSSION[5]

Only state actions that originally could have been filed in federal court may be removed to the federal court by

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[4] N.J.S.T. § 2A:58C-5 which states:

> Punitive damages shall not be awarded if a drug or device or food or food additive which cause the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

[5] The Magistrate Judge stresses to both parties the well known concept that less is more. The superfluous citing of cases that only

the defendant. 28 U.S.C. § 1441. The party removing the case to federal court bears the burden of proving that the federal court has jurisdiction. *Id.* The question of whether a claim "arises under" federal law must be determined by reference to the "well-pleaded complaint" rule, examining the well pleaded allegations of the complaint and ignoring potential defenses. 28 U.S.C. §§ 1331, 1441; *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d 318, 322 (6th Cir.2005). The well-pleaded complaint rule recognizes that the plaintiff is the master of his complaint. *Id.* Accordingly, if the plaintiff chooses to bring a state law claim, that claim cannot generally be "recharacterized" as a federal claim for purposes of removal. *Id.* However, while this rule makes the plaintiff the master of his claim, the plaintiff may not avoid federal jurisdiction by omitting from the complaint allegations of federal law that are essential to the claim. If the plaintiff does so, a court may recharacterize the "artfully-pleaded" complaint as though it had been "well-pleaded."

One narrow exception to the well-pleaded complaint rule is the doctrine of "complete preemption."[6] This doctrine permits removal of an action to federal court when a federal statute wholly displaces a state law cause of action. *Strong v. Teletronics Pacing Sys., Inc.*, 78 F.3d 256 (6th Cir.1996).

Another relatively new, and equally limited, exception to the well-pleaded complaint rule is substantial federal

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marginally advance arguments is unnecessary as is the continuous repetition of the same arguments.

[6] The Supreme Court has demonstrated a reluctance to extend the application of the "complete preemption" exception. See *Palkow v. CSX Transp., Inc.*, 431 F.3d 543, 553-54 (2005), for a detailed account of when the Supreme Court has applied this very limited exception, mainly for those claims involving LMRA and ERISA as well as usury and copyright laws.

issue preemption. The Supreme Court has recently held that there is federal question jurisdiction, even in the absence of an express or implied federal cause of action, if a substantial federal question of great federal interest is raised by a complaint framed in terms of state law, and if resolution of that federal question is necessary to the resolution of that state-law claim. *Merrell Dow Pharmaceuticals, Inc., v. Thompson,* 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986); *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing,* 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005).

A. Whether there is complete preemption

As the party invoking removal, and since the face of the Plaintiff's well-pleaded complaint does not state a federal claim, the Defendant bears the burden of establishing Plaintiffs' cause of action is completely preempted. Defendant asserted in it's Notice of Removal that this Court has jurisdiction under the doctrine of complete preemption because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medication that any challenge to such marketing and promotion necessarily states a federal cause of action: violation of the FDCA and its implementing regulations." (Case No. 3:06-1166, Docket Entry 15, Exhibit 3, ¶¶ 7, 8, and 9).[7] Plaintiffs responded in their Motion for Remand as well as in their reply brief that the complete preemption doctrine simply does not apply and that Defendant has cited no authority for this

[7] It should be noted that the Defendant did not advance it's complete preemption argument in it's Opposition to the instant Motion to Remand or during the January 22, 2007, hearing. However, given that it was originally one prong of Defendant's basis from removal, it is fully addressed in this Report and Recommendation.

assertion. (Case No. 3:06-1116, Docket Entry 15, Exhibit 14, Page 9-10, 12-13).

The Magistrate Judge agrees with the Plaintiffs. The Defendant confusingly blurs it's arguments regarding complete preemption which warrants removal with those of ordinary preemption of state law. Complete preemption that supports removal and ordinary preemption are two distinct concepts. *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d at 323 (citing 28 U.S.C. § 1441 and *Warner v. Ford Motor Co.*, 46 F.3d 531, 535 (6th Cir.1995)(en banc)). Complete preemption that permits removal is reserved for statutes designed to occupy the regulatory field with respect to a particular subject *and to create a superseding cause of action*, while ordinary preemption applies to statutory sections that arguably supersede conflicting state law. *Id.* (emphasis added). "In other words, the complete preemption doctrine is not simply one of preemption of the law, it is a sort of 'super' preemption which preempts not only the state law, but also creates federal jurisdiction-to use the jargon of the day, it is 'preemption on steroids.' " *Palkow v. CSX Transp., Inc.*, 431 F.3d 543, 553 (6th Cir.2005). Additionally, it is important to note that a case may not be removed to federal court on a the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987); *Baldwin v. Pirelli Armstrong Tire Corp.*, 927 F.Supp. 1046 (M.D.Tenn.1996).

It is now clear to the Magistrate Judge that the Defendant's arguments, while arguably supporting ordinary preemption of Plaintiffs' state law claims and/or federal question jurisdiction under substantial federal question

preemption as discussed in detail below, do not support a finding of complete preemption. "The congressional intent necessary to confer removal jurisdiction upon the federal district courts through complete preemption is expressed through creation of a parallel federal cause of action that would 'convert' a state cause of action into the federal action for purpose of the well-pleaded complaint rule." *Strong v. Teletronics Pacing Sys., Inc.*, 78 F.3d at 260; *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d 318 (6th Cir.2005). When Congress has indicated an intent to so completely occupy the field, any ostensibly state law claim is in fact a federal claim for purposes of arising-under jurisdiction. *Id.* Applying the standard to the instant matter, complete preemption does not apply as the FDCA does not create or imply a private right of action for individuals injured as a result of the violations of the Act.[8]

Given the limited number of statutes which the Supreme Court has found to "completely preempt" state law claims so as to permit recharacterization of a plaintiffs' claim as a federal claim so that removal is proper, as well as the Defendant's failure to cite to and the Mag-

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[8] Defendant has apparently made a similar arguments regarding misbranding and other labeling issues in previous litigation involving the use of the drug Elidel. *Perry v. Novartis Pharma. Corp.*, 456 F.Supp.2d 678 (E.D.Pa.2006). The Magistrate Judge notes that *Perry* was a diversity action and did not deal with the issue of remand. However, the FDCA conflict preemption analysis is still useful. Specifically, the Court found that, ". . . the bar to a finding of preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus, a finding of preemption here will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Courts have (understandably) been particularly reluctant to find preemption in such cases without an unambiguous signal of Congressional intent. Courts should therefore not reach to find that FDA regulations preempt state law claims." *Id.* at 684.

istrate Judge's inability to locate any cases which hold that labeling based claims under the FDCA are completely preempted, it is apparent that complete preemption should not be applied in the instant case. The fact that the Defendant might ultimately prove that Plaintiffs' claims are preempted under the FDCA does not establish that such state law based claims are now removable to federal court. See *Caterpillar,* 482 U.S. at 398.

B. Whether Plaintiffs' claims require the resolution of substantial federal issues

The Defendant also argues that federal question jurisdiction exists to support removal under the contours of 28 U.S.C. § 1331, as interpreted by recent Supreme Court holdings, which carve out a new, non-complete preemption form of federal question jurisdiction for purposes of removal of state law claims. *Palkow,* 431 F.3d at 554 (citing *Merrell Dow Pharmaceuticals, Inc. v. Thompson,* 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986)). The Supreme Court now allows for federal jurisdiction if there is a substantial federal issue raised by a state action based complaint, if resolution of that federal issue is necessary to the resolution of that state-law claim. *Merrell Dow,* 478 U.S. at 804; see also *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing,* 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005).

The Defendant argues that there are two main substantial federal issues raised by the Plaintiffs' state action based complaint that warrant federal jurisdiction: (1) Plaintiffs' references in the Complaint in Count IV (Negligence-Failure to Warn) to the Defendant's alleged violation of the FDCA regarding warnings and labeling[9]

[9] The Defendant cites a laundry list of possible federal issues related to this issue. (Case No. 06-1166, Docket Entry 15, Exhibit 11, Pages 11-12).

and (2) the Plaintiffs' claims for punitive damages which Defendant argues requires the Plaintiffs to prove "fraud on the FDA" as a prerequisite to recovery. Plaintiffs respond that all causes of action are based solely upon state law and do not require that they prove the Defendant violated any portion of federal law as an element of, or prerequisite to, any of their claims. Plaintiffs further respond that even if federal issues are involved, such issues are not substantial to an extent that they warrant federal jurisdiction. Again, the Magistrate Judge agrees with the Plaintiffs that their state based action does not warrant federal jurisdiction.

1. Count IV (Negligence-Failure to Warn)

Similar to the instant case, the Supreme Court, in *Merrell Dow Pharmaceuticals, Inc. v. Thompson,* found that a state court negligence action against a drug manufacturer resting in part on the allegation that the defendant drug company had violated a federal misbranding prohibition did not present a federal question, so that removal of the action to federal court was improper. 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986). The Supreme Court held that "a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under' " § 1331. *Id.* at 817. In short, Congress did not intend a private federal remedy for violations of the statute [the FDCA] that it enacted and therefore, the presence of a federal issue as an element of the state tort claim is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system. *Id.* at 814. The Supreme Court found, even assuming that federal law would have to be applied to resolve the claim, that fed-

eral jurisdiction was unavailable after closely examining the strength of the federal issue at stake and the implications of opening the federal forum. *Id.* at 817.

The Supreme Court further clarified *Merrell Dow* in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005). The Court stated that *Merrell Dow* could not be read to make a federal cause of action created by Congress a necessary condition for federal question jurisdiction.[10] Specifically, the Court reiterated that *Merrell Dow* "should be read in its entirety as treating the absence of such cause as evidence relevant to, but not dispositive of, the 'sensitive judgements about congressional intent' required by § 1331." *Id.* at 309 (citing *Merrell Dow v. Thompson*, 478 U.S. at 810). The Court stated that while it could not state a "single, precise, all embracing" test for jurisdiction over federal issues embedded in state-law claims between non-diverse parties, the question to ask is:

> Does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities?

The Court further detailed that in such cases, "federal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." *Id.* at 313. Additionally, because aris-

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[10] There was an apparent split between the circuits on whether the holding in *Merrell Dow* meant there must always be a federal cause of action as a condition for exercising federal-question jurisdiction. The Supreme Court in *Grable*, as described above, resolved this issue.

ing-under jurisdiction always raises the possibility of upsetting the division of labor between the state and federal courts, even when the state action raises a contested and substantial federal issue, this issue will only qualify for federal jurisdiction if it is "consistent with congressional judgment" on the proper division of labor between the two court systems. *Id.* The Court concluded stating that Merrell Dow's "analysis thus fits within the framework of examining the importance of having a federal forum for the issue, and the consistency of such a forum with Congress's intended division of labor between state and federal courts." *Id.* at 319.

In *Merrell Dow,* the Court held that a general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would have "heralded a potentially enormous shift of traditionally state cases into federal courts." *Grable v. Darue,* 545 U.S. at 319 (citing *Merrell Dow v. Thompson,* at 811-812). In *Grable,* the Court upheld this portion of it's decision in *Merrell Dow* stating: "For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases." *Id.* at 318.

The standards set by both *Merrell Dow* and *Grable* purposefully do not set clear jurisdictional boundaries. Rather, the Supreme Court has made it clear that each case involving an alleged violation of the FDCA must be reviewed to determine whether it should be distinguished on its facts from those in *Grable* and *Merrell Dow.* In the instant case, given the significance of the assumed Congressional preclusion of federal private remedies for misbranding under the FDCA as well as the "potentially enormous shift of traditionally state cases into federal courts," the Magistrate Judge finds any pos-

sible federal issues related to Plaintiffs' failure to warn claims, as alleged and described by both the Plaintiffs and the Defendant, do not rise to the kind of adjudication for which federal jurisdiction would serve congressional purposes and the federal system. *Grable v. Darue*, 545 U.S. at 319 (citing *Merrell Dow v. Thompson*, at 811-812). While the Magistrate Judge has reviewed the Defendant's list of *potential* federal issues,[11] given the Supreme Court's holdings in *Grable* and *Merrell Dow*, these are not substantial to the extent that the Plaintiffs' case rests on the resolution of these issues. In spite of Defendant's blanket assertions to the contrary, Plaintiffs' stated causes of action do not require proof of violation of federal law as an essential element to recovery.[12] *Grable v. Darue*, 478 U.S. at 814. The Magistrate Judge believes these issues, if they arise, could be properly handled by the state court as part of Plaintiffs' state law claims.[13]

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[11] Case No. 3:06-cv-01166 Docket Entry 15, Exhibit 11, Pages 11-12.

[12] It should also be noted that the Plaintiffs are not requesting that the Defendant modify it's label and related packaging in violation of FDA regulations nor are the Plaintiffs suing the FDA itself in this action.

[13] Interestingly, Defendant has made similar preemptive arguments when requesting a motion to dismiss, again in *Perry v. Novartis Pharmaceuticals Corp.*, 456 F.Supp.2d 678 (E.D.Pa.2006). The Court rejected Defendant's preemption arguments stating that:

> If at some future date, Congress determines that FDA monitoring is sufficiently effective on its own to warrant the elimination of state law incentives for manufacturers to provide adequate warnings, it also has the authority to declare that failure to warn suits, like the Perry's action, are preempted. Until it does so, however, in the absence of a specific FDA safety determination, such suits can go forward. *Perry*, 456 F.Supp. at 687.

Further, the Defendant argues at length that the novelty of these issues, especially in light of the recent FDA preamble,[14] justifies the retention of Plaintiffs' labeling based claims. However, in *Merrell Dow*, the Supreme Court clearly stated that:

> We do not believe the question whether a particular claim arises under federal law depends on the novelty of the federal issue. Although it is true that federal jurisdiction cannot be based on a frivolous or insubstantial federal question, 'the interrelation of federal and state authority and the proper management of the federal judicial system,' would be ill served by a rule that made the existence of federal-question jurisdiction depend on the district court's case-by-case appraisal of the novelty of the federal question asserted as an element of the state tort. The novelty of an FDCA issue is not sufficient to give it status as a federal cause of action; nor should it be sufficient to give a state-based FDCA claim status as a jurisdiction-triggering federal question. 478 U.S. at 817 (citing *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 8, 103 S.Ct. 2841, 77 L.Ed.2d 420 (1983).

Therefore, the novelty of any possible federal issues presented by the Defendant is clearly not sufficient to establish federal question jurisdiction.

2. Plaintiffs' claims for punitive damages

A more interesting argument is made by the Defendant related to Plaintiffs' punitive damages claims. However,

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[14] The *Perry* Court, in response to Defendant's reliance on the non-binding authority of the recent FDA preamble which arguably takes the position that its labeling requirements should have a pre-

while the Magistrate Judge agrees with the Defendant that state courts cannot step into the shoes of the FDA to determine whether a fraud on the FDA has been committed, Plaintiffs' claims for punitive damages still do not warrant federal jurisdiction, for reasons discussed in detail below.

The relevant portion of N.J. Stat. Ann. § 2A:58C-5(c) states: ". . . where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded."[15]

The Defendant makes the argument that Plaintiffs' claim for punitive damages raises a substantial federal question because New Jersey's punitive damages statute incorporates federal law by providing for a "fraud on the FDA" exception. The Defendant contends that the Plaintiffs are barred from recovering punitive damage unless the Plaintiffs establish the Defendant "knowingly withheld or misrepresented" material and relevant information to the FDA, which would require Plaintiffs to establish that the Defendant violated federal law in its submission of materials to the FDA.

Plaintiffs respond that their claims do not turn on a "fraud on the FDA claim," but rather that New Jersey law sets a standard where a plaintiff need only show that

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emptive effect (71 Fed.Reg. 3922 (Jan. 24, 2006)), persuasively stated that Congress, not federal agencies, have the power to preempt state law claims as "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Perry*, at 683 (quoting *Alexander v. Sandoval*, 532 U.S. 275, 291, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001). The Magistrate Judge agrees with the *Perry* Court's analysis on the deference to the FDA's preamble and advisory opinions and therefore, need not repeat it here at length. See *Perry*, 456 F.Supp. at 682-84.

[15] For the statute's full text, see footnote 4. 14

the drug company withheld information that was material and relevant to the harm in question in order to support a punitive damages claim. Plaintiffs assert that no inquiry into FDA procedures or analysis or speculation as to what the FDA would have done with the information is necessary.

The Supreme Court has expressly considered the question of a state common law fraud-on-the-FDA tort claim and has found that it is impliedly preempted by the FDCA. *Buckman Company v. Plaintiffs' Legal Committee,* 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). *Buckman* was a diversity case where the plaintiffs' theory of liability was that but-for the defendant's fraudulent statements to the FDA, the bone screws would have never received FDA approval, and the plaintiffs would not have been injured. 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). The Supreme Court found that, "Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.' " *Id.* at 347 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). Further, the Supreme Court found that state law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgement and objectives. *Id.* at 350. The Supreme Court was concerned that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA . . ." *Id.* Further, fraudon-the-FDA claims "would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of

information that the Administration neither wants or needs, resulting in additional burdens on the FDA's evaluation of an application" causing delays and impeding competition. *Id.* at 351.

In contrast to *Buckman*, the present case does not involve a claim of fraud-on-the-FDA but instead involves a state statute which immunizes drug manufacturers from punitive damage liability *unless* the plaintiff can prove fraud on the FDA. Stated differently, *Buckman* involved a specific cause of action for fraud on the FDA, whereas the instant Plaintiffs must prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under New Jersey law.

It appears that two other courts have considered this very same issue. In *Garcia v. Wyeth-Ayerst*, a diversity action, the plaintiff brought a products liability action against a drug manufacturer seeking punitive damages. 385 F.3d 961 (2004). Michigan, like New Jersey, immunizes drug manufacturers from punitive damage liability in actions based on injuries from FDA-approved drugs absent a showing that the drug manufacturers secured FDA approval through fraud. The Sixth Circuit held that the distinction between a plaintiff who brought a direct cause of action for fraud on the FDA and a plaintiff who had to prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under Michigan law was immaterial in light of *Buckman*. *Id.* at 965-66. The Sixth Circuit held that regardless of whether a plaintiff is required to prove fraud on the FDA as a cause of action unto itself or simply as a prerequisite in a punitive damages action, "such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* at 966 (citing *Buckman*, 531 U.S. at 351).

The Sixth Circuit did find that the Michigan law fraud exceptions, under *Buckman*, could be applied in certain

situations. "Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of a *state court* findings of fraud on the FDA . . . . [however those concerns stated in *Buckman]* do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* at 966. "Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into the law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings (e.g, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (e.g. claims based on federal findings of bribery or fraud on the FDA)." *Id.* Therefore, the Sixth Circuit found that the Michigan law did not conflict with the FDCA as long as the proof of the fraud-on-the-FDA element was satisfied only by a finding by the FDA itself that it had been defrauded. *Id.* at 966.[16] The Sixth Circuit concluded that absent such a finding by the FDA, the statute was unconstitutional but severable, placing "responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts." *Id.* at 967.

In *Kobar v. Novartis Corporation,* the same issue was presented as in *Garcia,* in the context of a similar Arizona statute, on a motion for partial summary judgment on the issue of punitive damages. 378 F.Supp.2d 1166 (2005). There, the Plaintiff made the same argument as the Plaintiffs in the instant case, i.e. that she did not

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[16] This is supported in *Buckman* by Justice Stevens, concurring: "If the FDA determines both that fraud has occurred and that such fraud requires the removal of products from the market, state damage remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." 531 U.S. at 354.

have to prove fraud on the FDA but rather merely that the drug manufacturer withheld "material and relevant" information from the FDA during the approval process. *Id.* at 1172-73. However, the *Kobar* Court was not persuaded by the distinction finding that: "Both common law fraud on the FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process." *Id.* The *Kobar* Court further stated that the "FDA is equally empowered to police and deter fraud with respect to the drug approval process . . . [and] the FDA has the authority to request additional information from a drug manufacturer, investigate suspected fraud, seek injunctive relief and civil penalties and pursue criminal prosecutions." *Id.* at 1173. As in *Garcia*, the *Kobar* Court found that severing the fraud exceptions from the rest of the Arizona statute would still allow a plaintiff to obtain punitive damages so long as the FDA itself made a finding that it has been defrauded by the drug manufacturer. *Id.* at 1176. Also as in *Garcia*, the *Kobar* Court found that the statute was unconstitutional in all situations except when the FDA makes a finding that it has been defrauded. *Id.* at 1174-75.[17]

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[17] The Second Circuit, interpreting the same Michigan law, has disagreed with the Sixth Circuit's holding in *Garcia*. In *Desiano v. Warner-Lambert & Co.*, the Second Circuit found that federal law did not preempt the punitive damages immunity exception. 467 F.3d 85 (2nd Cir.2006). The Second Circuit advanced that the immunity granted by the Michigan statute was in the form of an affirmative defense for drug manufacturers regarding punitive damage liability and that,

> "Finding preemption of traditional common law claims where fraud is not even a required element-but may be submitted to neutralize a drugmaker's use of an affir-

Neither *Buckman, Garcia* or *Kobar* address whether the request for punitive damages when there is a fraud-on-the-FDA exception is a substantial issue which warrants removal to federal court. Therefore, this is a novel issue presented to this Court. At this point, the Magistrate Judge goes back to the standard set by the Supreme Court in *Grable:*

> Does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities? 545 U.S. at 313.

Further, it is important to again note that a case may not be removed to federal court on a the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue. *Caterpillar Inc. v.*

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mative defense available under state law-would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." *Id.* at 96.

The Magistrate Judge respectfully disagrees with the Second Circuit's interpretation of the Michigan statute which provides drug manufacturer's, not with an affirmative defense, but with absolutely immunity regarding punitive damages absent a showing that the drug manufacturer secured FDA approval through fraud. For the reasons clearly outlined above, the Magistrate Judge believes that the FDA itself must make this finding of fraud.

Williams, 482 U.S. 386, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987). *Baldwin v. Pirelli Armstrong Tire Corp.*, 927 F.Supp. 1046 (M.D.Tenn.1996).

Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. The object of the New Jersey legislature in creating this statute was to regulate and restrict when Plaintiffs could recover punitive damages, which falls squarely within its prerogative to regulate matters of health and safety. Where Plaintiffs seek punitive damages under the New Jersey statute in either state or federal courts and the issue on fraud-on-the-FDA is raised, the potential would exist for the FDA's personnel to be drawn into those controversy on a case-by-case basis over and over again. This would generate a wholly impractical situation. Therefore, the Magistrate Judge believes that, in the instant case, the Plaintiffs, whether in federal or state court, will not be entitled to punitive damages absent a finding *by the FDA* that the Defendant committed fraud on the agency. The concerns expressed in *Buckman*, *Garcia* and *Kobar*, such as state courts having to step into the shoes of the FDA in making fraud determinations and the possible delay in the drug approval if applicants feared that their disclosures to the FDA although deemed appropriate by the Administration will later be judged insufficient in state courts, are also equally true if federal courts, on a federal district by federal district or even federal circuit by federal circuit, make determinations of fraud. As such, whether in federal or state court, the FDA will need to make a finding on the matter of fraud before the Plaintiffs will be entitled to recover punitive damages under New Jersey law.

With all of this said, it is the Magistrate Judge's belief that Plaintiffs' claims for punitive damages will not

require the New Jersey state court to find fraud-on-the-FDA and as such, no substantial federal issue is present which warrants federal jurisdiction. Rather, the Defendant will have to present a defense to the New Jersey state court, similar to the Defendants in *Garcia* and *Kobar*, that the portion of the New Jersey statute which requires Plaintiffs to demonstrate that "the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question" is preempted and can only be satisfied by an FDA finding of fraud. As noted above, this federal preemption defense is not sufficient to remove a state law complaint to federal court.

In summary, the Magistrate Judge believes that the Plaintiffs will be required to submit a finding by the FDA of fraud prior to being able to recover punitive damages in either state court or in federal court. While this specific issue preemption argument has not been presented in regards to the New Jersey statute in question, the Defendant can present such an argument as a defense in state court if needed. As such, there is no substantial issue presented regarding punitive damages which warrants federal jurisdiction.

C. Whether Plaintiffs are entitled to attorneys' fees

The Magistrate Judge believes that the Defendant had an objectively reasonable basis for seeking removal, when considering the combined effect of all of it's arguments regarding labeling as well as it's novel argument regarding punitive damages. Therefore, the Plaintiffs are not entitled to their attorneys' fees and costs incurred as a result of the removal. 28 U.S.C. § 1447(c).

IV. RECOMMENDATION

For the reasons stated above, the Magistrate Judge recommends that the Plaintiffs' Consolidated Motion for Remand be **GRANTED** and that Plaintiffs' causes of action be **REMANDED** to New Jersey state court. Further, the Magistrate Judge recommends that Plaintiffs' request for attorneys' fees be **DENIED.**

Under Rule 72(b) of the Federal Rules of Civil Procedure, any party has ten (10) days from receipt of this Report and Recommendation in which to file any written objections to this Recommendation, with the District Court. Any party opposing said objections shall have ten (10) days from receipt of any objections filed in this Report in which to file any responses to said objections. Failure to file specific objections within ten (10) days of receipt of this Report and Recommendation can constitute a waiver of further appeal of this Recommendation. *Thomas v. Arn,* 474 U.S. 140, 106 S.Ct. 466, 88 L.Ed.2d 435 (1985), *reh'g denied,* 474 U.S. 1111, 106 S.Ct. 899, 88 L.Ed.2d 933 (1986).

UNITED STATES DISTRICT COURT
D. MINNESOTA

No. MDL 01-1396 JRTFLN
Jan. 5, 2004

In re: ST. JUDE MEDICAL, INC. SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION

J. Gordon Rudd, Jr. and Charles S. Zimmerman, Zimmerman Reed, P.L . L.P., Minneapolis, MN, Steven E. Angstreich, Michael Coren, and Carolyn Lindheim, Levy, Angstreich, Finney, Baldante, Rubenstein & Coren, P.C., Woodcrest Pavilion, Cherry Hill, NJ, James T. Capretz, Capretz & Assoc., Newport Beach, CA, Joe D. Jacobson, Green, Schaaf & Jacobson, P.C., St. Louis, MO, and Patrick Murphy, Bochanis and Murphy Legal Associates, Las Vegas, NV, for plaintiffs.

Tracy J. Van Steenburgh, Halleland, Lewis, Nilan, Sipkins & Johnson, Minneapolis, MN, James C. Martin and David E. Stanley, Reed Smith Crosby Heafey LLP, Los Angeles, CA, Steven M. Kohn, Reed Smith Crosby Heafey LLP, Oakland, CA, for defendant.

MEMORANDUM OPINION AND ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

TUNHEIM, J.

On April 18, 2001, the cases making up this multidistrict litigation were transferred to this Court by the Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings under 28 U.S.C. § 1407. Defendant St. Jude Medical ("St. Jude" or "SJM") requests summary judgment, arguing that all plaintiffs' claims are preempted by federal law. Plaintiffs argue that key material fact questions prevent summary judgment. The motion was extensively briefed, and the Court heard lengthy argument on the matter. For the reasons discussed below, defendant's motion is denied.

BACKGROUND

I. Factual Background[1]

Defendant St. Jude, a company with headquarters and manufacturing facilities in Minnesota, manufactures a variety of medical devices including prosthetic heart valves. Such valves are surgically implanted into patients whose natural valves have been damaged by disease. Among St. Jude's products is the Silzone heart valve, which has a coating of silver on the sewing cuff,

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[1] In support of their respective positions, both parties submitted multi-volume Appendices. For ease of reference, the Court will cite to these Appendices as, for example, "Pl.App. Vol. *X* at Tab. *Y*." In addition, defendant submitted two affidavits not in Appendix form. Those will be referred to by the last name of the affiant, and the Tab (exhibit) number. Finally, the Court also cites to the parties' respective memoranda as "Def. Brief" or "Def. Reply" and "Pl. Brief."

the part of the valve that is sewn to the patient's body. Aside from the silver coating, the Silzone valve is essentially the same as other St. Jude heart valves that have been approved by the U.S. Food and Drug Administration ("FDA") since 1995. Silver has been known to have anti-microbial properties, and St. Jude introduced the silver-coated valves to combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a well-known possible consequence of prosthetic heart valve implantation.

The FDA approved the Silzone valve for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis, as no clinical tests had been performed to study this claim.[2] After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial ("AVERT") study, a multinational clinical trial designed to study whether the Silzone-coated heart valve reduced the incidence of endocarditis in humans. Approximately 36,000 Silzone valves have been implanted in patients worldwide, with approximately 10,535 of these in the United States. AVERT was originally intended to involve 4,400 heart valve patients. However, the study enrolled only 792 patients, with approximately half of those receiving Silzone-coated valves and another half, the control group, receiving conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more

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[2] The FDA also required that all labels bearing the name "Silzone" must carry the following statement: "No clinical studies have been performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis."

likely than recipients of conventional valves to experience a complication called paravalvular leak,[3] requiring the prosthetic valve to be removed and replaced with another valve. The data showed that two percent of AVERT participants with Silzone valves required such an "explant," while only .25 percent of participants with conventional valves required the procedure. On January 21, 2000, the monitoring board decided to suspend enrollment in the AVERT trial because of this increase in paravalvular leak.[4] On the same day, St. Jude voluntarily recalled all un-implanted Silzone products. As part of the recall, St. Jude notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis and treatment of paravalvular leak.

In response to the voluntary recall, the FDA informed St. Jude that its actions would be considered a "recall." *See* Plaintiffs' Appendix Vol. VI, Ex. 100, March 20, 2000, Memorandum from Cardiovascular and Neurological Devices Branch ("We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm's actions as a voluntary recall."). *See also* Plaintiffs' Appendix Vol. V, Ex. 24, March 22, 2000 letter from Edwin Dee to St. Jude ("We agree with your firm's decision to recall [the Silzone valve] . . . We have reviewed your action and conclude that it meets the for-

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[3] Paravalvular leak involves leakage at the point where a heart valve is sutured to a patient's tissue. *See* J.E. Schmidt, *Attorney's Dictionary of Medicine and Word Finder,* Vol. 4, P-79 (2002).

[4] Although enrollment in AVERT was suspended, the participants continue to be monitored and data are still collected and studied.

mal definition of a 'Recall'. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market.").

II. Statutory Regulatory Scheme

Regulation of medical devices is governed by the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976(MDA), 90 Stat. 539, 21 U.S.C. § 301. *See generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Devices are separated into three Classes (I, II, and III). The Silzone valve is a Class III device. Class III devices are defined as those devices that "presen[t] a potential unreasonable risk of illness or injury." § 360c(a)(c)(ii)(II). Because of the potential risks, Class III devices are subject to the strictest regulation of the three classes of devices. *Id.*

Typically, Class III devices must undergo an exhaustive review process with the FDA, called premarket approval (PMA) before they may be approved and marketed. The PMA "requires the applicant to demonstrate a 'reasonable assurance' that the device is both 'safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.' " *Buckman*, 531 U.S. at 344 (quoting §§ 360e(d)(2)(A), (B)).

There are also "exemptions" to the PMA process, one such exemption is the 510k exemption. The 510k process allows devices that are "substantially equivalent" to medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. See 21 U.S.C. § 360j(g)(1). This limited form of review "averages only 20 hours of

review as opposed to some 1200 hours in the PMA process." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir.2000) (herinafter "*Kemp*") (citing *Martin v. Telectronics Pacing Sys.*, 105 F.3d 1090, 1095 (6th Cir.1997); *Reeves v. AcroMed Corp.*, 103 F.3d 442, 446 (5th Cir.1997)).[5]

If the FDA approves a PMA, "it does so subject to conditions described in a document entitled 'Conditions of Approval.' " *Kemp*, 231 F.3d at 223. The Conditions of Approval form "requires manufacturers to submit the device's proposed labeling before marketing, limits advertising to the approved labeling, requires the manufacturer to submit a PMA supplement for review and approval before making any change affecting the safety or effectiveness of the device, requires the manufacturer to submit post-approval reports, and requires the manufacturer to report any incidents of adverse reaction to, or known defect of, the approved device." *Woods v. Gliatech, Inc.*, 218 F.Supp.2d 802, 805-06 (W.D.Va.2002).

FDA regulations provide that:

> FDA may impose postapproval requirements in a PMA approval order . . . Postapproval requirements may include as a condition to approval of the device: . . . (2) continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for

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[5] There is also an exemption for experimental or investigational devices (investigational device exemption or "IDE"). The IDE provides an exemption for devices representing innovative technology, and allows for unapproved devices to be utilized in human trials. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1.

> such requirement and the number of patients to be evaluated and the reports required to be submitted . . . (9) Such other requirements as FDA determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

21 C.F.R. § 814.82(a). "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80.

The FDA can withdraw approval if the manufacturer has not met all post-approval requirements, if the device is unsafe or ineffective, or if the PMA contained or was accompanied by an untrue statement of material fact. 21 U.S.C. § 360(e)(1) and 21 C.F.R. 814.46. At least one court has held that the failure to comply with PMA conditions invalidates FDA approval. *Woods*, 218 F.Supp.2d at 808 n.4.

III. Approval of the Silzone Valve

The Silzone valve was a modification to St. Jude's previously approved heart valve, as such, the Silzone valve itself did not go through the PMA process, but instead was approved via the "PMA Supplement" process.[6] 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39. *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir.2000) ("Should a manufacturer merely propose to modify a Class III device that has already received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submit-

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[6] The previously approved valve was the "Masters Series" valve, which itself was approved via a PMA supplement, rather than the full-blown PMA process.

ting the entire device for review.") *See generally United States v. Prigmore*, 243 F.3d 1, 5 (1st Cir.2001) (describing PMA supplement process). The PMA Supplement, like the initial PMA application "must contain scientific information that provides a basis for approval of the modified device." *Prigmore*, 243 F.3d at 5 (quoting 21 C.F.R. § 814.39(c)). *Id.* "All procedures and actions that apply to [a PMA] application under § 814.20 also apply to PMA supplements." § 814.39(c).

Defendant argues that approval pursuant to a PMA supplement is "sufficient evidence" that the device is "reasonably safe and effective for its intended use," and that therefore any claims based on the safety or efficacy of the device must be preempted. (Def. Brief at 17.) Defendant has submitted volumes of exhibits in support of its argument that the FDA carefully considered the approval, and that the PMA Supplement was exhaustive. For example, defendant submits exhibits indicating that St. Jude provided at least five "addendums" to the PMA Supplement. Each supplement addressed specific concerns voiced by FDA officials or consultants.

Despite this evidence, plaintiffs assert that FDA approval was improperly secured and unlawfully maintained. In support of this argument, plaintiffs submit the affidavits of three experts.[7] The gist of those affidavits is that St. Jude concealed information from the FDA, and that had that information been made available, the FDA would not have approved the valve. Plaintiffs suggest that because their claims are premised on the contention that St. Jude failed to comply with FDA regulations, there is no preemption. *See Brooks*, 273 F.3d at 798 ("a claim of failure to comply with FDA regulations is not preempted by the MDA, since such a state

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[7] These affidavits are the subject of a motion to strike, which is addressed below.

claim imposes no requirements different from, or in addition to any federal requirement") (internal quotation and citations omitted).

Plaintiffs also argue that although the approval was ostensibly PMA approval, in reality the FDA used a 510k-type approval (the much less intensive approval described above). The 510k process was at issue in *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996) (herinafter "*Lohr*") a case in which the Supreme Court determined that plaintiff's claims were not preempted. Citing *Lohr,* plaintiffs argue that because 510k approval is based on equivalence, not safety, their claims are not preempted. Finally, plaintiffs alternatively argue that the express preemption of 360k(a) cannot apply, because the device approved is actually a drug or drug/device combination, not a device. The distinction between drug and device, plaintiffs argue, is one for the Court. Plaintiffs suggest that the FDA never determined that the Silzone valve was a device, rather than a drug/device combination. Even if the FDA made such a determination, plaintiffs continue, this Court owes no deference to it because Congress, and not the FDA, divided medical implements into categories of either drug or device.

ANALYSIS

I. Standard of Review

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56. Only

disputes over facts that might affect the outcome of the suit under the governing substantive law will properly preclude the entry of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment is not appropriate if the dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* Summary judgment is to be granted only where the evidence is such that no reasonable jury could return a verdict for the nonmoving party. *Id.*

The moving party bears the burden of bringing forward sufficient evidence to establish that there are no genuine issues of material fact and that the movant is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The nonmoving party is entitled to the benefit of all reasonable inferences to be drawn from the underlying facts in the record. *Vette Co. v. Aetna Casualty & Surety Co.*, 612 F.2d 1076, 1077 (8th Cir.1980). However, the nonmoving party may not merely rest upon allegations or denials in its pleadings, but it must set forth specific facts by affidavits or otherwise showing that there is a genuine issue for trial. *Forrest v. Kraft Foods, Inc.*, 285 F.3d 688, 691 (8th Cir.2002).

II. Preemption Principles

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The principle of preemption is the application of this clause, resulting in the rule that any "state law that conflicts with federal law is 'without effect.' " *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Preemption is disfavored in areas of historic importance to the states' police powers-areas such as

public health and safety. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir.2000). *See also Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (no presumption against preemption where plaintiffs' claims involved medical devices, but were more accurately characterized as "fraud on the FDA" claims because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied") (internal quotation omitted).

Preemption is typically understood as having two types-express and implied. Express preemption is found when Congress "pre-empt[s] state law by so stating in express terms." *Hillsborough County, Fla. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 712-13 (1985) (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525). Implied preemption, in turn, has two types-field preemption, and conflict preemption. Field preemption occurs when Congress legislates so pervasively in a particular field that no room remains for concurrent state legislation. *Id.* Conflict preemption occurs

> [e]ven where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Id. (internal quotations omitted).

"Central to determining questions of preemption is divining Congress' intent." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir.2000) (citing *Cipollone*, 505 U.S. at 517-18). Courts must be careful to avoid the "unintended encroachment on the authority of the States" and

therefore "will be reluctant to find pre-emption" where the subject is one "traditionally governed by state law." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663-64 (1993). Where Congress has included an express pre-emption provision in a statute, courts historically have not looked beyond it to consider implied preemption. *Kemp*, 231 F.3d at 222. However, since *Buckman Co. v. Plaintiff's Legal Comm.*, it is clear that express and implied preemption are not mutually exclusive. Therefore, the Court discusses both express and implied pre-emption.

A. Express Preemption-Section 360k

At issue in these cases is the express preemption provision of the MDA, which states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).

1. What is a "requirement"

Courts have struggled to divine Congress's intent in § 360k-specifically, courts have differed in the understanding of what was meant by the term "requirement" in the context of a "requirement" imposed by a State (or political subdivision). Some courts have reasoned that "requirement" is intended to encompass only State legislative, statutory "requirements." *See Oja v. Howemed-*

ica, Inc., 111 F.3d 782, 789 (10th Cir.1997) (interpreting *Lohr* and holding that "requirement" meant only state statutory requirements). Others determined that the term "requirements" was intended to include common-law tort claims as well. *See, e.g., Martin*, 254 F.3d at 579-83; *Kemp*, 213 F.3d at 224.

These differing understandings stem from the Supreme Court's discussion of "requirements" in *Lohr*. Justice Stevens, writing for a plurality, rejected as "implausible" the medical device manufacturer's suggestion that "any common-law cause of action is a 'requirement' which alters incentives or imposes duties 'different from, or in addition to,' the generic federal standards." *Lohr*, 518 U.S. at 486-87. Justice Stevens discussed the language of § 360k, the legislative history, and the fact that members of both houses "were acutely aware of ongoing product liability litigation" when the section was enacted. *Id.* at 487-491. Stevens concluded that § 360k "simply was not intended to pre-empt most, let alone all general common-law duties enforced by damages actions." *Id.* at 491. Despite this discussion, Stevens did not "respond directly" to the plaintiff's contention that common-law duties are never requirements within the meaning of § 360k and that the statute therefore never pre-empts common-law actions. *Id.* at 502-03.

Justice Bryer, writing separately, noted that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 504. Bryer used the example of a federal regulation of hearing aids requiring a two-inch wire, and a state regulation requiring a one-inch wire. The state regulation would clearly be pre-empted, Bryer reasoned, therefore a jury award of damages based on the one-inch wire would also be pre-empted. *Id.*

The Supreme Court has revisited its holding in *Lohr* to insinuate that the term "requirement" in the MDA applies to tort claims as well as particular state statutory "requirements." *See Geier v. American Honda Motor Corp.*, 529 U.S. 861, 867 (2000) ("a majority of this Court has said that . . . a provision that uses the word 'requirements'—may well expressly pre-empt similar tort actions."). (Emphasis added) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502-04 (1996) (plurality opinion); *id.* at 503-05 (Breyer, J. concurring in part and concurring in judgment); *id.*, at 509-12 (O'Connor, J. concurring in part and dissenting in part)); *American Honda Motor Corp.*, 529 U.S. 861, 897 (2000) (Stevens, J. dissenting) ("And in *Medtronic v. Lohr*, we recognized that the statutory reference to 'any requirement' imposed by a State or its political subdivisions may include common-law duties.") (citations omitted) (emphasis added). Despite this language, there has been no explicit holding by the Supreme Court, in the medical device realm, that any particular common law claim has constituted a "requirement ."

Equally difficult has been determining what constitutes the federal requirement. At least two approaches have been put forth. Some courts have applied a process-oriented definition to the term "requirement." *See, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir.1997). Those courts reason that the PMA process itself, without more, constitutes the "requirement" mentioned in the statute. Another approach is to look at the device specific edicts from the FDA, and consider those edicts the "requirements" of 360k.

Some Courts have held that the PMA process itself is a federal "requirement" imposed by the MDA. *See Mitchell*, 126 F.3d 902 (holding that unlike the 510k process, the PMA process can constitute the sort of specific

federal "requirement" that can have preemptive effect under the MDA); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir.2001) (same). There is a division of authority, however, and the Eleventh Circuit has reached the opposite conclusion. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir.) *reh'g* and *reh'g en banc* denied (1999) (holding that the PMA process itself is not a "requirement" and reasoning that the ordinary construction of the language of 360k and use of the term "requirement" in the broader statutory context and the FDA regulations contemplate the imposition of some identifiable precondition that applies to the device in question); *Woods v. Gliatech, Inc.*, 218 F.Supp.2d 802 (W.D.Va.2002) (holding that PMA approval represents only a finding that the device manufacturer has reasonably assured the FDA of the safety and effectiveness, and also finding that PMA approval does not provide any indication of what, if any, specific substantive requirements the FDA may have applied to reach that result); *Webster v. Pacesetter, Inc.*, 171 F.Supp.2d 1, 19 (D.D.C.2001) (rejecting argument that PMA process amounts to a "requirement"); *Quillin v. American Hosp. Supply Co.*, 1997 WL 382095 (N.D.Okl., March 31, 1997) (PMA process does not constitute a "requirement" for the purpose of determining whether a plaintiff's state common law claims are preempted). The Supreme Court has not addressed the issue.

Prior to *Lohr*, the Eighth Circuit had held that the PMA process itself constituted a "requirement." *See Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir.1994). However, in *Brooks v. Howmedica*, the Eighth Circuit, sitting *en banc*, retreated from that broad holding. *See Brooks v. Howmedica*, 273 F.3d 785, 795 (8th Cir.2001), *cert. denied*, 535 U.S. 1056 (2002) (noting that the *Martello* holding "requires some modification"

to be consistent with the Supreme Court's decision in *Lohr*). The *Brooks* Court did not hold that the PMA process itself amounts to a requirement. Instead, the *Brooks* Court carefully compared the plaintiff's claims with the federal requirements and determined that "[t]he failure to warn claim [plaintiff] Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives. Because these 'particular state requirement[s] threaten[ ] to interfere with . . . specific federal interest[s],' *Lohr,* 518 U.S. at 500, 116 S.Ct. 2240, Brooks' claim is preempted by the MDA." *Id.* at 798 (alteration and internal quotation in original).

B. Applying express preemption

1. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr,* the Supreme Court first discussed whether the MDA preempts particular common law tort claims. 518 U.S. 470 (1996). The plaintiff in *Lohr* had received a pacemaker (a Class III device) that had been approved under the 510k process. Plaintiff asserted claims of negligence and strict liability against the manufacturer, alleging defendant had failed to use reasonable care during production. The Court, in a plurality opinion, held that none of plaintiff's claims were preempted. Specifically, the Court held that the MDA does not preempt state or local requirements that are equal to, or substantially identical to, requirements imposed under federal law. Similarly, the Court held that plaintiff's claims were not preempted to the extent that they alleged that the manufacturer failed to comply with duties equal to, or substantially identical to, federal requirements.

In response to the defendant's preemption argument, the *Lohr* Court emphasized that it would be "to say the

least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' and it would take language much plainer than the text of § 360k to convince us that Congress intended that result." *Id.* at 484 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)). The Court went on to note that, "[n]othing in 360k denies [States] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495.

Lohr generated confusion as the circuit courts attempted to discern its specific holding, and apply it in subsequent cases, including cases in which plaintiffs were injured by devices that had been approved through the full PMA process, and cases in which plaintiffs pled alternate theories of liability. *See Kemp,* 231 F .3d at 221 (noting that "[C]ourts of appeals that have confronted the issues of preemption arising under the MDA have struggled mightily with *Lohr's* language in the effort to discern its holding" and further noting that "[t]his appeal presents fractious issues which have sharply divided the various circuit courts which have considered them."). *Compare Kemp,* 231 F.3d 216 (granting summary judgment to pacemaker manufacturer on preemption grounds) *with Goodlin v. Medtronic, Inc.,* 167 F.3d 1367 (11th Cir.1999) (facts and legal theories almost indistinguishable, but refusing to find plaintiff's claims preempted).

2. *Brooks v. Howmedica*

In *Brooks v. Howmedica,* 273 F.3d 785 (8th Cir.2001), *cert. denied,* 535 U.S. 1056 (2002), the Eighth Circuit, sitting *en banc,* reversed its panel decision, and denied relief to a former orthopedic surgical nurse who had

been injured by repeated on-the-job exposure to toxins released as she mixed bone cement.[8] The *Brooks* court held that plaintiff's claims of negligent failure to warn and failure to comply with federal labeling regulations were expressly preempted.[9] In reaching this conclusion, the court discussed the extensive regulation to which defendant was subject, and noted that the approval process "included review by the FDA of the proposed design and content for all Simplex labels" and that "the FDA drafted the language that was used in the package insert." The court also emphasized that the case involved "ascertainable requirements" taking the form of "a series of mandates regarding the label" issued by the FDA. Under the *Brooks* analysis, such mandates amount to the federal "requirement" with which state "requirements" must not conflict.

The *Brooks* court articulated a "three-step test" to determine if a plaintiff's state law claim is preempted-first, discern the federal requirement imposed on a medical device manufacturer; next, determine the state requirement; finally compare the two to see if there is conflict. *Id.* at 794 (*"Lohr* instructs that state requirements—including common law duties-are preempted to the extent that they interfere with specific federal

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[8] It is noteworthy that the plaintiff in *Brooks* was in a different position than the typical plaintiff—that is, plaintiff Brooks was not a recipient of the medical device at issue, rather, her injuries were caused by mixing the bone cement to prepare the device for surgery.

[9] The Eighth Circuit mimicked the Supreme Court in declining to address the "other" preemption category—that is, the Supreme Court in *Buckman* stated in a footnote that because it found plaintiffs' claims impliedly preempted, it would not address express preemption. In *Brooks* the Eighth Circuit, also in a footnote, noted that "because we find express preemption, we do not address any potential issue of implied preemption." *Id.* at 792 n. 7.

requirements. The state and federal restrictions must be 'carefully compar[ed]' to ascertain whether there is interference between them—that being the 'overarching concern' of the test articulated by Justice Stevens and joined in by Justice Breyer.") (emphasis added) (quoting *Lohr*, 518 U.S. at 500).

C. Implied preemption - *Buckman Co. v. Plaintiffs' Legal Committee*

After *Lohr*, the Supreme Court next examined the issue of preemption in the MDA context in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, plaintiffs injured by orthopedic bone screws brought suit alleging that defendant, a regulatory consultant, had made fraudulent representations to the FDA in order to obtain approval to market the devices. The *Buckman* Court declined to address whether express preemption applied, holding that plaintiffs' "fraud on the FDA" claims were impliedly preempted. The Court noted that the FDA itself is charged with policing fraud on it and has a variety of enforcement options that allow it to make "a measured response to suspected fraud." *Id.* at 350. Therefore, the state fraud on the FDA claims conflicted with the FDCA—specifically, permitting plaintiffs' claims would conflict with the FDA's responsibility to police fraud consistently with its judgment and objectives.

In *Buckman*, despite the express preemption provision of 360(k) the Court found implied preemption applicable. In doing so, the Court did not clarify the confusion surrounding the appropriate use of implied versus express preemption. In fact, the Court specifically "express[ed] no view on whether the[ ] claims [were] subject to express pre-emption under 21 U.S.C. § 360k." *Id.* at 348 n. 2. The failure to address whether both types

of preemption could apply is significant, because, until *Buckman,* an oft-cited rule was that where express preemption applied, courts would not use the implied preemption theory. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not preempted.") (citations omitted). The *Buckman* Court also chose not to specify whether preemption analysis differs depending on the process through which the at-issue devices was approved (510k, PMA, or IDE).

Though instructive,[10] *Buckman* is distinguishable on several important grounds. First, the device approved in *Buckman* was approved via the 510k process, not the PMA/PMA Supplement process. In addition, the bone screws at issue in *Buckman* were being used "off-label" (they were approved for use in long bones, but were being used in back surgeries), an important distinction because Congress has repeatedly and explicitly noted that the FDA is not designed to interfere with practice of medicine. Plaintiffs in *Buckman* made only "fraud on the FDA claims." The Court specifically noted that states do not have a traditional interest in policing fraud on government agencies. The Court also emphasized that the MDA set up a comprehensive scheme for policing fraud, and that consumers could petition the FDA to take action against suspected wrongdoing. The harm complained of in *Buckman* was the fraud itself, as allegedly perpetrated

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[10] Defendant, while distinguishing a case from the Tenth Circuit, suggests that where a different method of approval is at issue (such as the 510k approval), the case "does not inform the issues before this Court." (Def. Brief at 10 n. 5.) The Court disagrees with this characterization, and finds useful those cases that involve other types of FDA approval, including *Buckman* and *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir.1997).

by the consulting group, not the plaintiffs' personal injuries. In fact, the manufacturer of the bone screws had settled with plaintiffs before the case was appealed to the Supreme Court. *See* Daniel W. Sigelman, *Is Fraud-on-the-FDA a Dead Letter After Buckman v. Plaintiffs' Legal Committee?*, 2 ATLA-CLE 2483 (2001) (noting that AcroMed Corporation, maker of the devices at issue, settled after Third Circuit's opinion). The remaining defendant was an FDA consultant who was not responsible for the design of the device, only for the manner in which the application was presented to the FDA.

III. Discerning the Federal "Requirements"

The parties understandably dispute the fundamental issue of what constitutes "requirements" of federal law in this case. This dispute is predictable, given the conflicting authority in both federal and state courts, as discussed above. The Court notes theoretical and practical difficulties in the "process" approach. Accepting the "process" argument-that the PMA Supplement process itself is a requirement-makes it difficult as a practical matter to find any claim that is not preempted. On a more theoretical level, this broad immunity is not consistent with Congressional intent in enacting the MDA, *see generally Lohr*, 518 U.S. at 490-92 (discussing congressional history), and is also not consistent with the presumption against preemption in areas of traditional state control (such as health and safety). *See id.* at 475 ("Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens."). Despite these shortcomings to the process approach, a majority of federal courts have held that the PMA/PMA Supplement process itself is a

"requirement." *See supra; see also Am. L. Prod. Liab.*3d § 91:16.

The Court finds that, given the language of § 360k and the implementing regulations,[11] the Supreme Court's rationale in *Lohr,* and the Eighth Circuit's reasoning in *Brooks v. Howmedica,* PMA Supplement approval, without more, is not necessarily a "requirement" of federal law. The submission of a product to the FDA for pre-market supplement approval does not, in itself, amount to a specific federal requirement meriting preemptive effect. Instead, the Court will inquire whether the FDA, in this instance, has promulgated any ascertainable precondition to regulatory approval. The Court will carefully examine the potential "federal requirements" and then compare those requirements to the relevant state laws.[12]

IV. Discerning the State Requirements and Comparing for Conflict

A. Strict liability and negligence claims

Plaintiffs allege that the Silzone valve was defective in design and/or formulation in that when the valves left

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[11] 21 C.F.R. § 808.1(d) "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements."

[12] The Court will address only the "main" claims common to the majority of plaintiffs. By not addressing a particular claim, the Court is not expressing an opinion on whether that ancillary claim would amount to a conflicting "requirement." However, defendant is not entitled to summary judgment on such claims, because defendant did not meet its burden of establishing that such claims conflict with a federal requirement.

defendant's hands the risks exceeded the benefits. Alternately, plaintiffs argue that the valves were defective in design or formulation in that they were more dangerous than an ordinary consumer would expect when used in their intended or reasonably foreseeable manner. Plaintiffs also allege the valves were defective due to inadequate warning, and that defendant failed to provide adequate post-marketing warnings. In addition, plaintiffs allege the valves failed to conform to the representation of defendant (in that they were not safe for use by consumers), and plaintiffs allege defendant failed to adequately test the valves.

Defendant argues that these claims are necessarily preempted because the FDA approved the device, and any inquiry into the approval process is forbidden "second-guessing" of the FDA. Plaintiffs argue that these claims are not pre-empted because the claims do not rely on any state "requirement" different from any federal requirement. Plaintiffs suggest that because there was no "requirement" to continue selling Silzone after its safety was called into question, plaintiffs' strict liability (and negligence) claims cannot be preempted.

Device manufacturers are never "required" to sell devices, and therefore it seems that plaintiffs' first argument would totally eliminate preemption—a result that clearly is incorrect. Plaintiffs' next argument, however, is more persuasive. Plaintiffs note that the FDA encourages voluntary recalls and unilateral changes to warning labels. Although the *Brooks* Court rejected an argument premising liability on the failure to update a warning, plaintiffs' argument is distinguishable. In *Brooks*, the Eighth Circuit examined the plaintiff's evidence to discern (1) whether the FDA was aware of that particular risk when approval to the warning language was granted and (2) whether that risk was scientifically established

either at the time of approval, or at the time the suit was brought. This inquiry implies that if the FDA had not been aware of the risk, plaintiff Brooks' failure to warn claim would not have been preempted. Applying that reasoning here, plaintiffs would have to establish that defendant knew of the particular risks during the PMA Supplement process, and that the risk is scientifically valid. Plaintiffs claim to have evidence of both, and point to specific facts in the record demonstrating a dispute of material fact.[13] Defendant has not, therefore, established that plaintiffs' strict liability failure to warn claims are pre-empted and summary judgment is inappropriate.[14]

Although the *Brooks* decision did not address a claim for design defect, the Court applies a similar rationale to deny defendant's motion for summary judgment as to those claims. As the Eighth Circuit explicitly stated in *Brooks*, a claim alleging failure to comply with FDA regulations is not preempted, because such a claim

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[13] Plaintiffs claim both pre-approval and post-approval evidence. Plaintiffs point to evidence that defendant misrepresented the results of animal tests to the FDA because defendant failed to report the death of one of the subject animals. In addition, plaintiffs cite public reports from the medical community of high rates of stroke and other thromboembolic events, as well as allegedly high explant patterns. Plaintiffs claim these facts establish knowledge on defendant's part that the valve was problematic, yet defendant did not report the problems to the FDA.

[14] Defendant's argument would allow medical device manufacturers to wrongfully withhold data from the FDA, gain PMA or PMA supplement approval, and then be completely immune from liability based on that approval. This cannot be what Congress had in mind when it enacted the MDA because, in its judgment, medical device manufacturers needed to be more strictly regulated. *See Lohr*, 518 U.S. at 587 (noting that in the judgment of Congress the medical device industry needed more stringent regulation).

imposes no requirements different from or in addition to federal requirements. *Brooks*, 273 F.3d at 798-99. Pre-emption was nonetheless appropriate in the *Brooks* case, however, because the Eighth Circuit determined that plaintiff did not make such a claim. In contrast, plaintiffs here claim, and present evidence, that defendant "violated federal regulations . . . failed to meet regular reporting requirements, failed to report a known hazard to the FDA, [and] failed to comply with federal law in other respects." *Id.* at 799. Therefore, to the extent that plaintiffs' negligence and defective design claims hinge on violations of FDA requirements, the claims are not preempted, and summary judgment is not appropriate.

B. Implied and Express Warranty

Plaintiffs allege that defendant breached the implied warranty because the Silzone valve was not fit and safe for its intended use, the defects were present when the product left defendant's hands and the valves were defective, unmerchantable and not fit for their intended purpose. To support their argument that the implied warranty claim is not pre-empted, plaintiffs point to section 808 of chapter 21 of the C.F.R. which notes that "[t]he following are examples of State or local requirements that are not regarded as preempted . . . requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code (warranty of fitness))." (Emphasis added.) Since many states, including Minnesota, have adopted the U.C.C. implied warranty provision, it appears that claims premised on the U.C.C. should survive preemption motions. *See Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330, n. 5 (4th Cir.1996) ("Although the [Supreme] Court did not address a claim

for breach of implied warranty in *Medtronic [v. Lohr]*, we nevertheless determine that the reasoning of that decision requires a conclusion that state-law claims for breach of implied warranties are not preempted by § 360k(a)."). *But see Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir.1997) ("If the [plaintiffs] meant to allege an implied warranty, it is preempted.").

Similarly, plaintiffs cite several cases in which courts have explicitly held that express warranty claims are not preempted. Those cases seem correctly decided and the Court agrees that express warranty claims are not preempted, at least to the extent that the defendant makes express warranties in addition to the language (warranties or warnings) required by the FDA. *See Mitchell*, 126 F.3d at 915 ("As we noted in our earlier opinion, [express] warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted."). *See also Steele v. Depuy Orthopaedics, Inc.*, 2003 WL 22779079 at (D.N.J. Nov. 20, 2003) (denying defendant's motion for summary judgment on preemption grounds as to plaintiff's breach of express warranty claims).

As evidence of particular express warranties that (allegedly) were breached, plaintiffs point to, among other things, an advertisement for Silzone which states, "With over 30,000 implants St. Jude Medical heart valves with Silzone coating continue our tradition of excellent clinical performance." Plaintiffs then note that in deposition, St. Jude employee Dr. Guzik admits that the "tradition of excellent clinical performance" was questionable. Plaintiffs argue this is a clear-cut example

of a breach of express warranty. Plaintiffs also assert, and support with deposition testimony, that St. Jude sales representatives represented to heart surgeons that the Silzone valves were superior to the Masters Series because of the anti-microbrial properties of the silver in the Silzone.[15] Such a representation was expressly forbidden by the FDA. St. Jude disputes that it made such representations, and points to statements by St. Jude managers to that effect. This disagreement highlights the disputed material facts. Plaintiffs have pointed to specific, admissible evidence raising disputed issues of material fact on these claims. Therefore summary judgment on pre-emption grounds must be denied as to the breach of warranty claims.

C. Inadequate warnings and labeling

Plaintiffs call this an "easy call" arguing that because Minnesota's duty to warn "requirements" mirror product manufacturers' duties under the FDCA and the FDA, there is no conflict. The trouble with plaintiffs' analysis is that the FDA, at least initially, determined that the labeling constituted an adequate warning. In fact, the FDA drafted some of the language, and approved all of the language.

Plaintiffs' argument continues—"despite knowledge [of risks] SJM never made or even proposed a single

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[15] For example, a St. Louis thoracic surgeon averred that he implanted approximately fifty Silzone valves "because of its asserted anti-bacterial and anti-infection properties." This understanding, he continues, "came in significant part from statements made to me by a sales representative of St. Jude Medical . . . [who] informed me that the Silzone valve was an improvement over the existing St. Jude Master's Series valve because the Silzone coating on the valve sewing cuff would greatly reduce the incidence of post-surgery infection." (Plaintiffs' Appendix at Volume VI, Exhibit 21).

change to the Silzone labeling." At first blush, this argument is identical to that rejected by the Eighth Circuit in *Brooks*. However, the plaintiff in *Brooks* could not show (or simply failed to show) that the FDA was unaware of the risks when the labeling was approved. Here, plaintiffs argue that they can demonstrate that the FDA was unaware of certain risks as the label language was updated. Defendant argues that plaintiffs' claims are nonetheless preempted, because to prove that the FDA was unaware of a given risk, plaintiffs will essentially have to prove fraud on the FDA-the inquiry rejected in *Buckman*. Defendant apparently would have the Court read *Buckman* so as to preempt any and all claims in which any inquiry into the FDA regulatory process is necessary.

It is difficult to accept such an expansive reading of *Buckman*, and such a reading would be difficult, if not impossible, to reconcile with the decision announced in *Lohr*. In addition, the *Brooks* Court had the benefit of the *Buckman* opinion, and nonetheless reasoned that the result might be different had plaintiff shown that the FDA was unaware of certain information. The Supreme Court in *Buckman* was addressing a cause of action emanating exclusively from federal regulations. This case does not present such a limitation. The critical distinction between *Lohr* and *Buckman* is not that a court or jury would have to examine what the FDA knew, and when it knew it. Instead the meaningful distinction is a fundamental difference in the very source of the cause of action. That is, in *Lohr*, the cause of action was based in traditional state tort law; in sharp contrast, the cause of action asserted in *Buckman* depended entirely on the regulatory relationship between the federal government and the FDA. In that dispositive way, the instant case is more similar to *Lohr*, and entirely unlike *Buckman*. In this

case, the inadequate labeling and failure to warn claims are based on traditional tort causes of action—causes of action that have normally been the exclusive province of states. For that reason, *Buckman* does not require preemption of these claims.[16]

Similarly, *Brooks* does not dictate a result in defendant's favor. Unlike the plaintiff in *Brooks*, the plaintiffs here have alleged, and have supported with specific evidence, that the FDA was not aware of the risk that the Silzone valve presented. In short, plaintiffs have raised disputed issues of material fact such that their inadequate warning and labeling claims survive summary judgment on the ground of preemption.

D. Consumer fraud & deceptive trade practices statutes

Like state law requirements under the U.C.C., the applicable regulation expressly states that claims under state unfair trade practices are not preempted. 21 C.F.R. § 808(d). Citing *Buckman*, defendant argues that plaintiffs' consumer fraud and deceptive trade practices claims are really "fraud on the FDA claims" in disguise, and are therefore preempted. Again, the Court does not find that *Buckman* extinguishes plaintiffs' claims at this stage of the litigation. Instead, the Court finds this case

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[16] Legal commentators have made a similar distinction. *See, e.g.*, Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 Washburn L.J. 549, 572 (2002) ("Under *Medtronic [v. Lohr]* and its predecessors, plaintiffs should ordinarily be able to base actions against manufacturers of risky products on traditional common law negligence and strict liability theories without fear of preemption. As cases based upon negligence and strict liability go forward, evidence of attempts by the defendant to manipulate the regulatory process through fraudulent or misleading means should be admissible even if wrongful manipulation may not support an independent claim for relief.").

more analogous to *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA*, 145 F.Supp.2d 565 (D.N.J.2001). In that case, the Court rejected defendant's preemption argument, noting:

> Plaintiffs' Complaint here does not allege a claim of "fraud on the FDA," but rather alleges that Defendants deceived the public, including Plaintiffs. The Supreme Court in *Buckman* expressly distinguished "fraud on the FDA" claims from other state tort claims for fraudulent labeling, such as those that the Court had previously addressed in *Medtronic v. Lohr*, 518 U.S. 470 (1996). *Buckman*, 121 S.Ct. at 1020. . . . *Buckman* thus clarified that traditional state tort law claims (even those which parallel FDCA requirements) are not necessarily preempted by the FDCA and are not necessarily the same as "fraud on the FDA" type claims. *Id.* Unlike the claims in *Buckman*, a finding of a violation of the FDCA is not a necessary element of Plaintiffs' claims, which rely on traditional state tort principles. Plaintiffs are not claiming a violation of the FDCA; their claims are confined to traditional state tort and fraud claims, similar to those in *Medtronic*.

Id. at 573. The Court finds that reasoning persuasive, and therefore denies defendant's pre-emption motion on the consumer fraud and deceptive trade practices claims.

E. Medical monitoring

In general, a medical monitoring plaintiff must establish exposure to a hazardous substance; that as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease; that increased risk makes periodic diagnostic medical examinations reasonably necessary, and that monitoring

and testing procedures exist which make the early detection and treatment of the disease possible and beneficial. The parties' briefing did not address whether medical monitoring claims impose requirements different from or in addition to those imposed by federal requirements, and the Court determines that such claims do not. Therefore, defendant's motion for summary judgment is denied as to plaintiffs' medical monitoring claims.

V. Drug, Device, or Both

Plaintiffs also assert that they have raised a disputed issue of material fact as to whether the valve is a device, or is a combination drug and device. This distinction is important because the express preemption principles and case law discussed above do not apply to combination products or to drugs (§ 360k by its terms applies only to devices). Plaintiffs base this argument on their experts' opinions that the silver sewn into the valve interacts with the body more like a drug than a device. Plaintiffs assert that the FDA never determined that the valve is a device, rather than a drug, but that even if such a determination had been made, the Court is not bound by the FDA's determination. *See Tarallo v. Searle Pharmaceutical, Inc.*, 704 F.Supp. 653, 658 (D.S.C.1988) (reasoning that because Congress defined the terms "drugs" and "device" the Court is not bound by an administrator's determination); *see also Callan v. G.D. Searle & Company*, 709 F.Supp. 662, 666 (D.Md.1989) (finding that Copper 7 IUD was drug due to release of copper ions).

Defendant briefly addresses this argument, and states the FDA expressly considered the drug/device issue and classified the valve as a device. The Court reviewed the exhibits defendant identified, and from those exhibits, it appears that the FDA *considered* the drug or device issue. In particular, one exhibit defendant identifies is a

portion of minutes from a June 1998 meeting, apparently of the Circulatory Systems Devices Panel of the FDA. Def. Appendix C, tab 32. That excerpt includes a discussion during which the drug/device distinction was addressed, but, at least in the portion submitted to the Court, there does not appear to be a conclusion or consensus reached. Defendant also suggests that all of Appendix C supports its argument that the FDA expressly determined that the valve is a device. The Court carefully reviewed the documents submitted in Appendix C, and did not uncover any indication that the FDA explicitly determined that the valve is a device, rather than a drug. The Court notes, however, that Appendix C does contain many instances of defendant making that assertion to the FDA, and the FDA continually referred to the valve as a device.

The Court owes no deference to an FDA "classification" where it is made simply for "administrative convenience" and does not reflect the considered view of the agency. *See Tarallo,* 704 F.Supp. at 658. The Court finds plaintiffs' argument that the valve more closely resemble a drug/device combination to be intuitively persuasive. However, because the Court finds that plaintiffs' claims are not pre-empted and this drug/device issue requires more extensive analysis, the Court will not decide at this time whether the heart valve with Silzone coating is a drug, a device or a combination.

VI. What approval? 510k or PMA Supplement

Plaintiffs finally argue that because the approval process here was more like the abbreviated 510k-equivalence process than the PMA Supplement-safety process, preemption should not apply. *See Brooks,* 273 F.3d at 794 ("Section 510(k) approval is a mere grant to market; it imposes no "requirements" of its own.") (Citing *Lohr,*

518 U.S. at 493). Plaintiffs suggest that the Court simply needs to determine that the FDA never made a determination of the efficacy of the Silzone coating.

The FDA, at least ostensibly, approved the valve via the PMA Supplement. (March 24, 1998 Letter from Susan Alpert, Director, Office of Device Evaluation stating "The Center for Devices and Radiological Health (CDRH) of the [ ] FDA has completed its evaluation of your premarket approval application (PMA) supplement."). On the other hand, it is clear that the FDA never determined that the Silzone coating was "effective." In fact, the FDA explicitly precluded defendant from making claims regarding the efficacy of the Silzone coating. *Id.* ("[T]he labeling of the device must not contain or imply any claims that the Silzone Coating is effective in reducing the incidence of endocarditis."). Equally clear, nonetheless, is that the valve itself continued to be considered effective as a heart valve. The parties ask the Court to determine if issuing a PMA Supplement approval without making a finding of efficacy, invalidates the approval, transforms the approval into 510(k) approval, or is an abuse of agency discretion.

A separate, but related argument is that the approval, whichever approval it was, was lost when defendant failed to comply with FDA guidelines, or if not at that point, at least once the product was voluntarily recalled. "Please comply with the above guidelines. We do not want to do anything that will jeopardize our own FDA approval." (Memorandum from Hosek to U.S. Sales Force at Plaintiffs' Appendix Vol. VI, Ex. 79.)

The FDA classified St. Jude's actions as "a recall." The Administration noted, "We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm's actions as a voluntary recall. We consider the devices to be adulterated and misbranded." (March 20,

2000, Memorandum from Cardiovascular and Neurological Devices Branch at Plaintiffs' Appendix Vo;. VI, Ex. 100.) Similarly, a March 22, 2000 letter from Edwin Dee to St. Jude noted, "We agree with your firm's decision to recall [listing of specific device identifying numbers] . . . We have reviewed your action and conclude that it meets the formal definition of a 'Recall'. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market." (Plaintiffs' Appendix Vol. V, Ex. 24.)

Defendant suggests that this letter is "out of context" and that the Silzone valve in fact has never been recalled (specifically, counsel for St. Jude stated at oral argument that "[T]he adulterated and defective language that the plaintiffs pick on from the correspondence is drawn out of context. It doesn't represent any regulatory finding or conclusion."). The Court hesitates to characterize defendant's argument too harshly, however, it is difficult to read the FDA's March 20, 2000 and/or March 22, 2000 correspondence and find any ambiguity, regardless of context. The FDA clearly indicates that the device is "adulterated and misbranded." The recall is significant because it is "an alternative to [FDA] legal action to remove the product from the market." Despite defense counsel's arguments, St. Jude appears to recognize that the Silzone valve is not marketable absent additional approval from the FDA. *See Affidavit of Alan Flory* at Plaintiffs' Appendix, Vol. II, Tab. 2(A) page 258. (Q: "The fact that the PMA Supplement has not been withdrawn doesn't mean that you're perfectly free to go out and market this product again, unless FDA says you can do it. Isn't that fair?" A: "That's true. . . . Unless we put in a PMA supplement and notify [the FDA] that we

have the clinical data that we said we would gather before we put it back on the market.")

The Court finds persuasive plaintiffs' argument that the Silzone valve no longer has FDA approval. At this time, however, the Court need not determine how the withdrawal of approval impacts plaintiffs' claims. Similarly, the Court will not resolve whether the Silzone valve's approval was via the PMA supplement or was 510k approval, because the Court has found that plaintiffs' claims are not pre-empted. The Court will not scrutinize such an involved issue without the benefit of thorough briefing on this specific question. The Court's research has revealed that plaintiffs' argument regarding types of approval (PMA versus 510k) is not novel, but the Court has been unable to find a reported decision in which a court analyzes the method of approval to determine independently whether the approval was PMA or 510k. *See, e.g., Steele v. Depuy Orthopaedics, Inc.*, 2003 WL 22779079 at (D.N.J. Nov. 20, 2003) (acknowledging plaintiffs' argument that the approval at issue was more akin to the abbreviated 510k, and apparently rejecting the argument, but not discussing the issue).

MOTIONS TO STRIKE

I. Defendant's motion to strike affidavits of plaintiffs' three experts

Defendant moves to strike the affidavits of Gregory Wilson, Devin Healy, and Suzanne Parisian, arguing that the expert reports violate "fundamental rules of evidentiary admissibility." Defendant asserts four "compelling reasons" to strike the affidavits, including (1) the opinions are irrelevant, (2) the expert's testimony is not the proper subject of expert opinion under controlling

law, (3) the opinions are simply legal conclusions "recast as expert opinion," and (4) the experts are not qualified.

For the purposes of this motion, the Court denies the motion to strike. The material is relevant, and the Court assures defendant that the Court will reach its own conclusions regarding the law and will not be misled by plaintiffs' experts. The Court might well be more cautious in allowing a jury to consider such opinions. Finally, the Court finds that the experts are adequately qualified given each expert's education, training and experience.

II. Plaintiffs' Motion to Strike the Affidavits of Alan Flory and Diane Johnson.

Flory is an employee of St. Jude Medical. Johnson is a former FDA employee who is presented as having expertise in the field of heart valve regulation and the PMA process. Plaintiffs object on the grounds of hearsay and lack of personal knowledge. Plaintiffs note that in deciding a motion for summary judgment, the Court may not consider affidavits that do not satisfy the requirements of Fed.R.Civ.P. 56(e).

Plaintiffs argue that the information in Flory's affidavit is based on hearsay. In addition, plaintiffs suggest that Flory admitted during deposition that he has no personal knowledge that St. Jude complied with every applicable FDA regulatory requirement as he averred. The basis for the objection to the Johnson affidavit appears to be lack of personal knowledge.

The Court denies the motion to strike for purposes of this summary judgment motion. Although the Court must not rely on evidence which would be inadmissible, it is not necessary to strike either affidavit. Plaintiffs have preserved their objections, and the Court can sift through the affidavits to determine what portions, if any, would

be inadmissible and therefore will not be considered for the purposes of summary judgment. It appears to the Court that Johnson is offered as an expert, and therefore the personal knowledge objection is inapplicable.

III. Plaintiffs' motion to strike the attachments to defendant's reply brief

The Court granted defendant a significant page and time extension for its reply brief. Defendant used its full page allotment, and also attached additional argument, in the form of "charts" as exhibits. These exhibits are improper, and given the Court's reasonableness in granting the page and time extension, the Court finds defendant's additional argument in the guise of "exhibits" unfortunate. The Court therefore strikes the argumentative portions of the "charts" (specifically, the portions preceding the numbered tabs). However, the charts also serve as a table of contents, and the Court will continue to use the table of contents portion.

ORDER

Based upon the foregoing, the submissions of the parties, the arguments of counsel and the entire file and proceedings herein, IT IS HEREBY ORDERED:

1. Defendant's motion for summary judgment [Docket No. 67] is DENIED;

2. Defendant's motion to strike the affidavits of Gregory John Wilson, Kevin E. Healy, and Suzanne Parisian [Docket No. 219] is DENIED.

3. Plaintiffs' motion to strike the affidavits of Alan R. Flory and Diane Johnson [Docket No. 208] is DENIED.

4. Plaintiffs' motion to strike appendices to St. Jude's reply in support of motion for summary judgment [Docket No. 223] is GRANTED in part and DENIED in part as described above.

IN THE DISTRICT COURT OF
HARRIS COUNTY, TEXAS
157th JUDICIAL DISTRICT

Filed April 20, 2007
(Trial Court: 151st Dist. Court of Harris County,
Cause No. 2005-58543)

RUBY LEDBETTER

—v.—

MERCK & CO., INC.

Order Granting Defendant's Motion for Partial Summary Judgment And Granting Expedited Appeal

Defendant Merck & Co., Inc. ("Merck") has filed a no evidence motion for partial summary judgment on plaintiff's warning claims. This motion is based on a 2003 Texas statute governing FDA approved warnings. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007. Merck argues that § 82.007 is preempted by federal law. For reasons stated, the motion is granted.

1. Background

Vioxx (known generically as rofecoxib) is a NSAID (non-steroidal anti-inflammatory drug). This class of drugs includes over the counter medications, such as Advil (ibuprofen) and Aleve (naproxen) and a variety of prescription medicines. NSAIDS work by inhibiting cyclo-oxygenase (COX), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects.

In the early 1990s, scientists discovered that the COX enzyme was composed of two forms. COX-1 affects the synthesis or production of prostaglandins responsible for protection of the stomach lining; COX-2 stimulates the prostaglandins that cause pain and inflammation. This belief led to the hypothesis that a selective NSAID, designed to inhibit COX-2, but not COX-1, could offer pain relief without the risk of fatal or debilitating gastrointestinal perforations and ulcers. This led Merck to begin the development of such a drug, which became known as a COX-2 inhibitor. Vioxx is a COX-2 inhibitor.

In December 1994, Merck submitted an Investigational New Drug Application to the FDA seeking approval to conduct studies to test the safety of Vioxx to treat osteoarthritis, rheumatoid arthritis, and pain. In November 1998 Merck submitted a New Drug Application for Vioxx. The FDA reviewed the Merck submission and, as well, convened an Advisory Committee to review the data and make recommendations. On May 20, 1999, the FDA approved Vioxx for sale in the United States.

Vioxx was subjected to a number of studies and trials, including VIGOR, APPROVe, and others. APPROVe was a randomized clinical trial that compared Vioxx to a placebo. The APPROVe study indicated that the use of

Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarctions.

On September 30, 2004, Merck withdrew Vioxx from the market. Thousands of lawsuits ensued across the country. On September 6, 2005, Texas cases were consolidated into this MDL proceeding. There are currently over 1,000 Vioxx cases in these consolidated Texas proceedings; virtually all of them contain an allegation that Merck failed to provide an adequate warning.

2. Preemption

A. The Texas Act

In 2003, the Texas legislature enacted TEX. CIV. PRAC. & REM. CODE ANN. § 82.007, which provides, in part:

> **§ 82.007. Medicines**
>
> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or

> Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended; or
>
> * * * *
>
> (b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:
>
> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;
>
> * * * *

TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (hereinafter the "Texas Act"). The Texas Act was one of a number of enactments in 2003 designed to achieve "tort reform" as a result of a perceived lawsuit crisis, particularly involving the medical arena. This statute has yet to be construed by Texas appellate courts.

There is no question but that the FDA approved the general warnings or information provided by Merck with respect to Vioxx. Plaintiffs rely exclusively upon subsection (b)(1) of the Texas Act in order to rebut the Act's presumption that Merck is not liable for failure to provide an adequate warning.

B. Construction of the Texas Act.

In order to determine whether the Texas Act has been preempted, this Court must first construe the various terms contained in the Act.

1. Burden of Proof.

A threshold question confronting this Court concerns the burden of proof under the Texas Act. Section 82.007 states that a claimant may rebut the presumption in the statute by "establishing" that certain required information was withheld. What does "establish" mean? Merck equates "establish" with "prove" and argues that plaintiffs must prove that such information was withheld or misrepresented by a preponderance of the evidence. Plaintiffs argue that the presumption "bursts" merely upon presenting some evidence that information was withheld. Thus, according to plaintiffs, at the conclusion of plaintiffs' case, the Court would rule as a matter of law whether some evidence of withholding or misrepresentation of evidence was presented, and thereafter, the failure to warn question would be presented to the jury. Plaintiffs therefore argue that the court, rather than the jury, decides whether information was withheld.

The Court agrees with Merck. Plaintiffs have the burden to "establish" or prove that required information was withheld from or misrepresented to the FDA by a preponderance of the evidence. This is ordinarily a question for the jury.

2. Required Information

To rebut the presumption, plaintiffs must show that "required information" was withheld or misrepresented. "Required information" means that information which is required to be submitted to the FDA pursuant to federal statute and regulations governing pharmaceutical products.

3. Material Information.

The Texas Act next requires that claimants prove that "material and relevant" information was withheld. Not surprisingly, the parties presented two different definitions of materiality.

- Plaintiffs posit that they must merely show "that the allegedly withheld information, if disclosed, would have a natural tendency to influence, or be capable of influencing, a government function."
- Merck, on the other hand, argues that plaintiffs must show "that the allegedly withheld information, if disclosed, in reasonable probability would have led to a different regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change."

Plaintiffs proposed definition is erroneous for several reasons. First, the definition would effectively make any relevant information sufficient to eliminate the presumption. Under the plaintiffs definition, virtually any information would qualify. Since the Texas Act was promulgated in an environment of tort reform, the legislature surely meant that the burden on plaintiffs be more than merely finding "some information" that "might" be capable of influencing the FDA. This Court may consider the circumstances surrounding a statute and the goals sought to be achieved by the legislature in construing a statute. *See Lexington Ins. Co. v. Strayhorn*, 209 S.W.3d 615 (Tex. 2005).

Second, the Texas Act requires that the withheld information be "causally related" to the plaintiff's injury. Unless withheld information would have resulted in some definite change by the FDA, either non-approval of the

drug, or a labeling change, such with withheld information could not be causally related to a plaintiff's injury.

Thus, plaintiffs must prove by a preponderance of the evidence that required information was withheld from or misrepresented to the FDA, such that the allegedly withheld or misrepresented information, if disclosed or not misrepresented, would have led to a different regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change.

4. Relevant information

The allegedly withheld or misrepresented information must relate to the same injury complained of by plaintiff.

C. Preemption of the Texas Act

The starting point of any preemption analysis concerning the Texas Act is *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001), where the Supreme Court held that state law "fraud on the FDA" claims are preempted by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA"). There, Buckman was a consulting company that assisted a manufacturer to obtain FDA approval for certain medical devices. Plaintiffs were consumers of these devices, who claimed personal injuries; plaintiffs sued Buckman alleging that Buckman made fraudulent representations to the FDA. Plaintiffs claimed that such misrepresentations were a "but for" cause of injuries: had the representations not been made, the FDA would not have approved the device, and plaintiffs would not have been injured. The Supreme Court held that such claims are preempted by the FDCA. The Court reasoned that it is the FDA's exclusive responsibility to "police fraud consistently with the Administration's judgment and objectives." *Id.*

at 350. The Court observed that the FDA is empowered to investigate fraud and that citizens may report wrongdoing and petition the agency to take action. *Id.* at 349. Moreover, "fraud-on-the FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court" resulting in a "deluge" of needless information on the FDA, potentially burdening the agency and delaying release of new products. *Id.* at 351.

Since *Buckman,* several courts have considered statutes similar to the Texas Act. In *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit considered a Michigan law that immunizes a drug manufacturer from products liability suits if the drug was approved by the FDA unless the manufacturer intentionally withheld or misrepresented required information.[1] The court held the Michigan law was preempted

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[1] The statute provides, in relevant part: "(5) In a product liability action against a manufacturer or a seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . . This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act. . . , and the drug would have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5).

to the extent that it permitted a state court to determine whether a drug manufacturer committed fraud on the FDA. *Id.* at 966. However, such "inter-branch-meddling concerns that animated *Buckman*" do not arise when the "FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* (emphasis in original) Thus, the court held that a plaintiff could only invoke the "fraud on the FDA" exception to the Michigan statute if the FDA itself determines that it was defrauded. Other courts have reached similar conclusions. *See, e.g., Henderson v. Merck & Co.*, 2005 WL 2600220 (E.D. Pa., Oct. 11, 2005); *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1172-74 (D. Ariz. 2005).

Plaintiffs, however, rely on *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), which reached a different conclusion and suggested three reasons why the *Garcia* analysis is flawed. First, plaintiffs correctly note that there is a presumption against preemption. While such a presumption exists, *see Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), the Supreme Court in *Buckman* expressly held that no such presumption against preemption existed in that case. "The relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." 531 U.S. at 347. Because, in that case, the medical device manufacturer's dealings with the FDA were prompted by federal law, "no presumption against preemption obtains in this case." *Id.* The same analysis must apply with no less force to drug manufacturers. Indeed, the State of Texas, by enacting the Texas Act, has placed the relationship between drug manufacturer and FDA in issue.

Second, plaintiffs argue that *Buckman* is inapplicable since it involved a non-traditional suit based entirely on a fraud on the FDA theory, whereas these suits allege traditional products liability theories. This is a distinction without a difference. Under the Texas Act, in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA. Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply. The requisite showing under the Texas Act is analogous to and sufficiently equivalent to plaintiffs' asserting a claim of fraud on the FDA that the claim is preempted under *Buckman*.

Finally, plaintiffs argue that the proof required under the Texas Act is different from a "fraud on the FDA" complaint. Plaintiffs argue that mere inadvertent withholding of information is sufficient to puncture the rebuttable presumption of the Texas Act[2], whereas intentional fraud was at issue in *Buckman*, and, indeed, part of the statute in Michigan. This Court is not persuaded by this argument. The logic of *Buckman* was that the FDA promulgates detailed data submission requirements and is fully empowered to investigate wrongful withholding by manufacturers. 531 U.S. at 1017. If anything, the argument that *Buckman* involved a claim with an element of scienter, whereas the Texas Act requires only inadvertent withholding undermines plaintiffs' argument. State courts traditionally adjudicate a party's state of

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[2] The Court notes that the Texas Act uses the word "misrepresents" which could imply an element of intent, depending on whether the misrepresentation required is intentional or negligent. However, for purposes of this motion, the Court will assume no scienter is required since the statute disjunctively includes "withheld from" as sufficient to eliminate the statutory rebuttable presumption.

mind, *e.g.*, whether fraud occurs. Indeed, a state court is probably better suited than a federal agency to determine whether an intentional misrepresentation occurred as opposed to an inadvertent omission. The key issue for purpose of presumption analysis is not whether information was intentionally withheld, but whether the federal regulation is so pervasive as to leave no room for state regulation. Given the extent of federal regulation, and the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas jury or judge to make the same inquiry would impinge on a uniquely federal issue.

All of the concerns raised by the Supreme Court in *Buckman* would manifest themselves if the motion for summary judgment were denied. *Buckman* noted that manufacturers might "deluge" the FDA with information it neither needed nor wanted in order to defend state tort claims. 531 U.S. at 351. This could potentially impede the regulatory process. The *Buckman* concern of deluging the FDA could well come true if manufacturers were forced to make data submissions defensively in order to ensure that the presumption of the Texas Act remained in place.

There is no question but that the FDA has not made a determination that material and relevant information was either withheld or misrepresented concerning Vioxx.

C. Severability

Plaintiffs argue that if subsection (b)(1) is preempted, then the entirety of section 82.007 must fall, leaving no presumption that Merck's is not liable with respect to the allegations involving failure to provide adequate warnings. This argument fails. First, plaintiffs can still avail themselves of (b)(1) if the FDA determines that required

information was withheld. The issue is who makes the determination—the FDA or a Texas court or jury.

Second, the Texas Act is severable. Texas law currently provides that:

> (c) in a statute that does not contain a provision for severability or nonseverability, if any provision of the statute or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the statute that can be given effect without the invalid provision or application, and to this end the provisions of the statute are severable.

TEX. GOV'T. CODE § 311.032(c). Unless the legislature provides for nonseverability, the Government Code provides that the statute is severable. Even if subsection (b)(1) is invalid, the remaining statute can be given effect.

Finally, in passing the Texas Act, the legislature expressly considered the possibility that the law would not survive a *Buckman* analysis.[3] Yet, notwithstanding this forewarning, the legislature did not insert a nonseverability provision into § 82.007.

D. Conclusion on Preemption

For the forgoing reasons, Merck's motion for partial summary judgment is granted and subsection (13)(1) of TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 is preempted to the extent that someone other than the FDA is being asked to make the determination. Plaintiffs cannot

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[3] For example, Baylor Law School Dean Bradley Tobin testified in Senate committee hearings that § 82.007 could very well be challenged on *Buckman* grounds. Hearings on Tex. H.B. 4 Before Senate State Affairs Comm., 78th Leg., R.S. at 23-24 (May 5, 2003).

rely on subsection (b)(1) unless and until the FDA makes the required findings under (b)(1).

3. Merck's Alternative Motion

Merck argued alternatively that even if the Texas Act is not preempted, a no evidence motion for summary judgment should nevertheless be granted. Merck argues that plaintiffs do not have sufficient evidence to rebut the presumption.

In response, plaintiffs submit the affidavits of various experts. However, because of this Court's ruling on preemption, it is not necessary to rule on Merck's alternative motion.

Plaintiff's motion to strike Merck's Summary Judgment evidence is Denied.

Plaintiff's claim of failure to warn is hereby severed from this Master Docket and will henceforth be under cause number 2005-59499A and in the original trial court as Cause No. 2005-58543A. The pleadings in this severed cause shall consist of plaintiff's petition(s), defendants' answer(s), Merck's motion for partial summary judgment and all responses, replies, rebuttals and other briefs and memoranda concerning the motion for summary judgment.

This is a final order and is appealable.

It is further ordered that any appeal from this Order be expedited pursuant to Tex. R. Jud. Admin. 13.9(c) as this order is made in MDL pretrial proceedings.

Signed April 19, 2007.

/s/ HON. RANDY WILSON
Hon. Randy Wilson

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case: 01-73249
Judge: Gerald E. Rosen
Magistrate Judge Morgan

CONNIE ARMSTRONG, LAURANANE BRADLEY and RAYMOND BRADLEY, GLENN CHANDLER, BILLIE FLYNT, SHELLY GROTENHUIS, JUDY HEARN, COLLEEN HERNDON and MICHAEL W. HERNDON, MICHAEL KANAKRY and MARY ANN KANAKRY, JULIA MARTIN and ROYAL M. MARTIN, JANICE L. KIMMEL, Personal Representative of the Estate of Thea Martz, Deceased, MONA PRZYTULSKI, DAVID A. RICE, Personal Representative of the Estate of Robert Rice, Deceased, ANITA SCHULTZ and RICHARD P. SCHULTZ, JAMES K. SOUKUP, Personal Representative of the Estate of Barbara Soukup, Deceased, JENNIFER ST. PIERRE, Personal Representative of the Estate of Raymond St. Pierre, Deceased, DONALD WAUN and JEANENE WAUN,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY AND PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

Complaint and Demand For Jury Trial

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and for their complaint against the defendants, state as follows:

1. That the plaintiff, Connie Armstrong, is a resident of the City of Flint, County of Genesse, State of Michigan.

2. That the plaintiffs, Lauranane Bradley and Raymond Bradley, are residents of the City of Ypsilanti, County of Washenaw, State of Michigan.

3. That the plaintiff, Glenn Chandler, is a resident of the City Ownedale, County of Huron, State of Michigan.

4. That the plaintiff, Billie Flynt, is a resident of the City of Flint, County of Genesee, State of Michigan.

5. That the plaintiff, Shelly Grotenhuis, is a resident of the City of Holland, County of Allegan, State of Michigan.

6. That the plaintiff, Judy Hearn, is a resident of the City of Detroit, County of Wayne, State of Michigan.

7. That the plaintiffs, Colleen Herndon and Michael W. Herndon, are residents of the City of Canton, County of Wayne, State of Michigan.

8. That the plaintiffs, Michael Kanarky and Mary Ann Kanakry, are residents of the City of St. Clair Shores, County of Macomb, State of Michigan.

9. That the plaintiffs, Julia Martin and Royal M. Martin, are residents of the City of Shelbyville, State of Tennessee.

10. That the plaintiff, Janice L. Kimmel, Personal Representative of the Estate of Thea Martz, Deceased, is a resident of the City of Midland, County of Midland, State of Michigan and that plaintiff's decedent, Thea Martz, at all times pertinent hereto, was a resident of the City of Midland, County of Midland, State of Michigan.

11. That the plaintiff, Mona Przytulski, is a resident of the Township of East China, County of St. Clair, State of Michigan.

12. That the plaintiff, David A. Rice, Personal Representative of the Estate of Robert Rice, Deceased, is a resident of the City of Battle Creek, County of Calhoun, State of Michigan and that at all times pertinent hereto, plaintiff's decedent, Robert Rice, was a resident of the Rochester Hills, County of Oakland, State of Michigan.

13. That the plaintiffs, Anita Schultz and Richard P. Schultz, are residents of the City Hudson, County of Lenawee, State of Michigan.

14. That the plaintiff, James K. Soukup, Personal Representative of the Estate of Barbara Soukup, Deceased, is a resident of the City of Mesick, County of Wexford, State of Michigan and that at all times relevant hereto, plaintiff's decedent, Barbara Soukup, was a resident of the City of Cadillac, County of Wexford, State of Michigan.

15. That the plaintiff, Jennifer St. Pierre, Personal Representative of the Estate of Raymond St. Pierre, Deceased, is a resident of the City of Fenton, County of Genesee, State of Michigan and that at all times relevant hereto, plaintiff's decedent, Raymond St. Pierre, was a resident of the City of Grand Blanc, County of Genesee, State of Michigan.

16. That the plaintiffs, Donald Waun and Jeanene Waun, are residents of the City of Warren, County of Macomb, State of Michigan.

17. That defendant, Warner-Lambert Company, is incorporated in the State of Delaware with its principal place of business being Morris Plains, New Jersey.

18. That defendant, Parke-Davis, a division of Warner-Lambert Company, is a Delaware Corporation with its principal place of business in Morris Plains, New Jersey, and thus, there is diversity between the plaintiffs and defendants.

19. That the amount in controversy exceeds the jurisdictional amount of Seventy-Five Thousand ($75,000.00) Dollars.

20. That plaintiffs and plaintiffs' decedents were consumers were prescribed who ingested the drug Rezulin, chemically known as Troglitazone.

21. That the defendants, Warner-Lambert Company, and Parke-Davis, a division of Warner-Lambert Company, are either manufacturers themselves or by use of others did manufacture, create, design, test, label, supply, promote, advertise, warn, and otherwise distribute in the United States the product Rezulin, chemically known as Troglitazone.

22. That defendants are manufacturers of Rezulin, chemically known as Troglitazone, and had a duty to plaintiffs and plaintiffs' decedents to warn of the dangerous medical side effects of said drug; however, the defendants did the following negligent, fraudulent, misrepresentation and product defect related acts (breach of warranty; breach of fitness for intended purpose):

A. Failed to use due care in designing and manufacturing Rezulin so as to avoid risks to individuals when Rezulin was being used for treatment of Type II Diabetes.

B. Failed to accompany their product with proper and timely warnings regarding all possible adverse side effects associated with the use of Rezulin and the comparative severity and duration of such adverse effects, and/or the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

C. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Rezulin.

D. Failed to provide adequate training to medical care providers for appropriate use of Rezulin.

E. Failed to warn plaintiffs and plaintiffs' decedents prior to actively encouraging the sale of Rezulin, either directly or indirectly, orally or in writing, about the following:

i. The need for comprehensive regular medical monitoring to insure early discovery of potentially fatal liver and/or cardiac side effects;

ii. The possibility of death as the result of liver failure or heart failure.

F. Engaged in deceptive and misleading practices, including withholding information from consumers, physicians and the FDA about the adverse event reports confirming liver and heart damage and the deaths associated with the drug.

G. Continued to aggressively publicize Rezulin as having side effects comparable to a placebo even though the defendants' company's own clinical trial data which had been submitted to the FDA as part of a new drug application indicated that patients in clinical trials develop liver problems four times as often as the controls who had received a placebo.

H. Withheld information from consumers, their doctors and the FDA to insure the continued success of what had become a billion dollar blockbuster drug. Sales of Rezulin to approximately two million diabetics generated revenues estimated at over $1.8 billion dollars.

23. That the defendants' product was unsafe for its intended use and was defective by reason of design, distribution, manufacturing, promotion, testing, and lack of adequate warnings, knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market.

WHEREFORE, plaintiffs, pray for relief as follows:

1. For general damages for each plaintiff in a sum in excess of the jurisdictional minimum of this court.

2. Medical, incidental, hospital, and service expenses according to proof.
3. Loss of earnings and earning capacity.
4. Pre-judgment and post-judgment interest as provided by law.
5. Full refund of purchase costs incurred by plaintiffs and plaintiffs' decedents for Rezulin.
6. Compensatory damages in excess of the jurisdictional minimum of the court, according to proof.
7. Consequential damages in excess of the jurisdictional minimum of the court, according to proof.
8. Exemplary/punitive damages.
9. Attorney fees, expenses, and costs of this action.
10. Such further relief as this court deems necessary, just and proper.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
Attorneys for Plaintiff
5510 Woodward Avenue
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(313) 875-8080

August 20, 2001

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case: 01-73249
Judge: Gerald E. Rosen
Magistrate Judge Morgan

CONNIE ARMSTRONG, LAURANANE BRADLEY and RAYMOND BRADLEY, GLENN CHANDLER, BILLIE FLYNT, SHELLY GROTENHUIS, JUDY HEARN, COLLEEN HERNDON and MICHAEL W. HERNDON, MICHAEL KANAKRY and MARY ANN KANAKRY, JULIA MARTIN and ROYAL M. MARTIN, JANICE L. KIMMEL, Personal Representative of the Estate of Thea Martz, Deceased, MONA PRZYTULSKI, DAVID A. RICE, Personal Representative of the Estate of Robert Rice, Deceased, ANITA SCHULTZ and RICHARD P. SCHULTZ, JAMES K. SOUKUP, Personal Representative of the Estate of Barbara Soukup, Deceased, JENNIFER ST. PIERRE, Personal Representative of the Estate of Raymond St. Pierre, Deceased, DONALD WAUN and JEANENE WAUN,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY AND PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiff
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

DEMAND FOR JURY TRIAL

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and hereby demand a trial by jury of the within cause.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
Attorneys for Plaintiffs
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August 20, 2001

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case No. 00-71806
Judge: Gerald E. Rosen
Magistrate Judge Capel

KIMBERLY KENT, Personal Representative of the Estate of Virginia Kent, Deceased, Emmett Kent on behalf of themselves and all other similar situated,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY AND PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

CLASS ACTION COMPLAINT AND DEMAND FOR JURY-TRIAL

NOW COME the plaintiffs, Kimberly Kent, Personal Representative of the Estate of Virginia Kent, Deceased, and Emmett Kent, individually and as class representatives, by and through their attorneys, CHARFOOS & CHIRSTENSEN, P.C., and for their complaint against the defendants, states and follows:

1. That the plaintiffs, Kimberly Kent, Personal Representative of the Estate of Virginia Kent, Deceased, and Emmett Kent are residents of the City of Detroit, County of Wayne, State of Michigan, United States of America.

2. That defendant, Warner-Lambert Company, is incorporated in the State of Delaware with its principal place of business being Morris Plains, New Jersey.

3. That defendant, Parke-Davis, a division of Warner-Lambert Company, is a Delaware Corporation with its principal place of business in Morris Plains, New Jersey, and thus, there is diversity between the plaintiffs and defendants.

4. That the amount in controversy exceeds the jurisdictional amount of Seventy-Five Thousand ($75,000.00) Dollars.

5. That plaintiff's decedent was a consumer and brings this action pursuant to F.R.Civ.P. 23 on behalf of all similarly situated persons in the United States who were prescribed and who ingested the drug Rezulin, chemically known as Troglitazone.

6. That the defendants, Warner-Lambert Company, and Parke-Davis, a division of Warner-Lambert Company, are either manufacturers themselves or by use of others did manufacture, create, design, test, label, dis-

tribute, supply, promote, advertise, warn, and otherwise distribute in the United States the product Rezulin, chemically known as Troglitazone.

7. That defendants are manufacturers of Rezulin, chemically known as Troglitazone, and had a duty to plaintiff's decedent, Virginia Kent, and other members of the class who are/were similarly situated to warn of the dangerous medical side effects of said drug, however, the defendants did the following negligent, fraudulent, misrepresentation and product defect related acts (breach of warranty; breach of fitness for intended purpose):

A. Failed to use due care in designing and manufacturing Rezulin so as to avoid risks to individuals when Rezulin was being used for treatment of Type II Diabetes.

B. Failed to accompany their product with proper and timely warnings regarding all possible adverse side effects associated with the use of Rezulin and the comparative severity and duration of such adverse effects, and/or the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

C. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Rezulin.

D. Failed to provide adequate training to medical care providers for appropriate use of Rezulin.

E. Failed to warn plaintiff's decedent and all others similarly situated prior to actively encouraging the sale of Rezulin, either directly or

indirectly, orally or in writing, about the following:

i. The need for comprehensive regular medical monitoring to insure early discovery of potentially fatal liver and/or cardiac side effects;

ii. The possibility of death as the result of liver failure or heart failure.

8. That the defendants' product was unsafe for its intended use and was defective by reason of design, distribution, manufacturing, promotion, testing, and lack of adequate warnings, knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market.

A. Engaged in deceptive and misleading practices, including withholding information from consumers, physicians and the FDA about the adverse event reports confirming liver and heart damage and the deaths associated with the drug.

B. Continued to aggressively publicize Rezulin as having side effects comparable to a placebo even though the defendants' company's own clinical trial data which had been submitted to the FDA as part of a new drug application indicated that patients in clinical trials develop liver problems four times as often as the controls who had received a placebo.

C. Withheld information from consumers, their doctors and the FDA to insure the continued success of what had become a billion dollar

blockbuster drug. Sales of Rezulin to approximately two million diabetics generated revenues estimated at over S1.8 billion dollars.

CLASS ACTION INJUNCTIVE EQUITABLE RELIEF

I. Medical Monitoring.

9. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows on behalf of themselves and all other similarly situated.

10. As a direct and proximate result of the defendants' acts, omissions and conduct as set forth above, plaintiff's decedent and each class member have been exposed to a hazardous substance and as a result suffer a significantly increased risk of serious injury or latent disease including liver and heart damage. This increased risk makes periodic diagnostic and medical examinations reasonable and necessary.

11. Easily administered, cost-effective monitoring and testing procedures exist which make the early detection and treatment of such injuries or disease possible and beneficial. For example, administration of a readily available, non-invasive test to diagnose the presence of liver or heart damage.

12. The recommended testing procedures will be subject to expert testimony at the time of trial. Appropriate testing regimes, based upon claimant information received from class members, will likely include non-invasive readily administrable initial tests and procedures, tailored to the individual claimant: e.g. echocardiograms, blood tests and liver function studies.

13. Many individuals at risk for liver and/or heart damage cannot afford to get appropriate testing and/or have not been advised and do not otherwise know of a need to undergo testing. Class members also need to be advised of the availability of non-invasive testing as a diagnostic tool and treatment which will prevent even graver injury.

14. The increased susceptibility to injuries and irreparable threat to the health of class members resulting from their exposure to Rezulin can only be mitigated or addressed by the creation of a comprehensive medical monitoring program:

A. Notifying consumers who used Rezulin of the potential harm from said drug;

B. Funding from further studies of the long term effects on users for Rezulin;

C. Funding research and possible cures for the detrimental effects of using Rezulin;

D. Gathering and forwarding to treating physicians information related to the diagnosis and treatment of injuries which may result from using Rezulin and;

E. Aiding in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of Rezulin users.

15. Rezulin users without present serious injury have no adequate remedy at law in that monetary damages do not compensate for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injury and aids in their treatment can prevent greater harms which may not occur immediately and which may be preventable if proper research is con-

ducted and the health risks are diagnosed and treated before they occur or become worse.

16. Plaintiff's decedent and class members' susceptibility to liver and heart damage is the significant result of their use of Rezulin. Early detection and diagnosis of these diseases is clinically invaluable since it can prevent or significantly delay resulting discomfort, disease and/or death.

17. Without a court-approved medical monitoring program, Rezulin users will not receive prompt medical care that could detect problems and prolong their productive lives, increase prospects for improvement minimize disability.

II. Updated Patient Warnings and Emergency Notice.

18. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows on behalf of themselves and all other similarly situated.

19. Defendants have a continuing duty to warn the class and the public of all potential risks and dangers of which they become or should become aware. There are studies underway regarding these risks and dangers. As a proximate result of the defendants' conduct described herein, plaintiff's decedent, on behalf of herself and all others similarly situated, are entitled to damages and/or equitable relief in the form of revised warnings, or equivalent remedial and corrective action, to accurately reflect the known adverse side effects of Rezulin, including liver and/or heart damage, even though Rezulin has been withdrawn from the market.

20. Defendants should be required to provide continuously updated product warnings to individuals who use and/or have previously used Rezulin for the treatment of Diabetes to provide them with timely information concerning effective testing and treatment options for those suffering from, or at risk for, liver and/or heart damage or other injury caused by Rezulin.

WHEREFORE, plaintiffs, pray for relief as follows:

A. Class-wide relief.

1. That this action and the causes of action asserted be certified as a class action on behalf of the proposed class of consumers who have ingested Rezulin and that the named plaintiffs be designated as representative of the class and that the named counsel be designated class counsel.

2. Creation of a comprehensive, court-supervised medical monitoring which will include:

a. Insure early diagnosis and treatment of resulting liver and heart injuries through ongoing testing and monitoring of Rezulin users;

b. Notify consumers who use or used Rezulin of the potential liver and heart damage from Rezulin;

c. Fund further studies of the long term liver and heart effects on Rezulin users;

d. Fund research and possible cures for the detrimental liver and heart effects of using Rezulin;

e. Gather and forward to treating physicians information related to the diagnosis and treatment of liver and heart damage which may result from using Rezulin; and

f. Provide class members with revised drug warnings and emergency notice.

3. The designation of any additional classes and subclasses and the appointment of any additional class representatives that the court may deem necessary or appropriate in connection with its class certification determinations including, but not limited to, the designation of classes, subclasses and/or class representatives with respect to each of the named defendants.

4. Award general, special and punitive/exemplary damages as well as attorney fees, expenses and costs of this action, including the costs of notices to the class.

B. Individual relief for individual plaintiffs.

1. For general damages for plaintiff and each class member in a sum in excess of the jurisdictional minimum of this court.

2. Medical, incidental, hospital, and service expenses according to proof.

3. Loss of earnings and earning capacity.

4. Pre-judgment and post-judgment interest as provided by law.
5. Full refund of purchase costs incurred by plaintiff's decedent and the members of the class for Rezulin.
6. Compensatory damages in excess of the jurisdictional minimum of the court, according to proof.
7. Consequential damages in excess of the jurisdictional minimum of the court, according to proof.
8. Exemplary/punitive damages.
9. Attorney fees, expenses, and costs of this action.
10. Such further relief as this court deems necessary, just and proper.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
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5510 Woodward Avenue
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(313) 875-8080

Dated: April 17, 2000

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case No. 03-70501
Judge: Gerald E. Rosen
Magistrate Judge R. Steven Whalen

LINDA SHERMAN and STANLEY SHERMAN,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY and PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

COMPLAINT AND DEMAND FOR JURY TRIAL

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and for their complaint against the defendants, state as follows:

1. That the plaintiffs, LINDA SHERMAN and STANLEY SHERMAN, are residents of the City of Onsted, County of Lenawee, State of Michigan.

2. That defendant, Warner-Lambert Company, is incorporated in the State of Delaware with its principal place of business being Morris Plains, New Jersey.

3. That defendant, Parke-Davis, a division of Warner-Lambert Company, is a Delaware Corporation with its principal place of business in Morris Plains, New Jersey, and thus, there is diversity between the plaintiffs and defendants.

4. That the amount in controversy exceeds the jurisdictional amount of Seventy-Five Thousand ($75,000.00) Dollars.

5. That plaintiffs were consumers who were prescribed and who ingested the drug Rezulin, chemically known as Troglitazone.

6. That the defendants, Warner-Lambert Company, and Parke-Davis, a division of Warner-Lambert Company, are either manufacturers themselves or by use of others did manufacture, create, design, test, label, supply, promote, advertise, warn, and otherwise distribute in the United States the product Rezulin, chemically known as Troglitazone.

7. That defendants are manufacturers of Rezulin, chemically known as Troglitazone, and had a duty to plaintiffs and plaintiffs' decedents to warn of the dan-

gerous medical side effects of said drug; however, the defendants did the following negligent, fraudulent, misrepresentation and product defect related acts (breach of warranty; breach of fitness for intended purpose):

A. Failed to use due care in designing and manufacturing Rezulin so as to avoid risks to individuals when Rezulin was being used for treatment of Type II Diabetes.

B. Failed to accompany their product with proper and timely warnings regarding all possible adverse side effects associated with the use of Rezulin and the comparative severity and duration of such adverse effects, and/or the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

C. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Rezulin.

D. Failed to provide adequate training to medical care providers for appropriate use of Rezulin.

E. Failed to warn plaintiffs and plaintiffs' decedents prior to actively encouraging the sale of Rezulin, either directly or indirectly, orally or in writing, about the following:

   i. The need for comprehensive regular medical monitoring to insure early discovery of potentially fatal liver and/or cardiac side effects;

   ii. The possibility of death as the result of liver failure or heart failure.

F. Engaged in deceptive and misleading practices, including withholding information from con-

sumers, physicians and the FDA about the adverse event reports confirming liver and heart damage and the deaths associated with the drug.

G. Continued to aggressively publicize Rezulin as having side effects comparable to a placebo even though the defendants' company's own clinical trial data which had been submitted to the FDA as part of a new drug application indicated that patients in clinical trials develop liver problems four times as often as the controls who had received a placebo.

H. Withheld information from consumers, their doctors and the FDA to insure the continued success of what had become a billion dollar blockbuster drug. Sales of Rezulin to approximately two million diabetics generated revenues estimated at over $1.8 billion dollars.

8. That the defendants' product was unsafe for its intended use and was defective by reason of design, distribution, manufacturing, promotion, testing, and lack of adequate warnings, knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market.

WHEREFORE, plaintiffs, pray for relief as follows:

1. For general damages for plaintiffs in a sum in excess of the jurisdictional minimum of this court.

2. Medical, incidental, hospital, and service expenses according to proof.

3. Loss of earnings and earning capacity.

4. Pre-judgment and post-judgment interest as provided by law.
5. Full refund of purchase costs incurred by plaintiffs and plaintiffs' decedents for Rezulin.
6. Compensatory damages in excess of the jurisdictional minimum of the court, according to proof.
7. Consequential damages in excess of the jurisdictional minimum of the court, according to proof.
8. Exemplary/punitive damages.
9. Attorney fees, expenses, and costs of this action.
10. Such further relief as this court deems necessary, just and proper.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
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January 5, 2003

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case No.
Judge

LINDA SHERMAN and STANLEY SHERMAN,
Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY and PARKE-DAVIS,
a division of Warner-Lambert Company, Delaware
Corporations, Jointly and Severally,
Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiff
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

DEMAND FOR JURY TRIAL

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and hereby demand a trial by jury of the within cause.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
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January 5, 2003

(6) (2)

No. 06-1498

FILED
JUL 20 2007
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SUPREME COURT, U.S.

In The

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
AND PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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SUMMARY OF THE ARGUMENT

This case is unlikely to have far-reaching effects: It is limited to Michigan drug-injury cases brought within the Second Circuit, in which a plaintiff can make a showing of fraud on the FDA; the statute at issue is subject to repeal by a bill that has passed one House of the Michigan Legislature and is pending in the other; and there is no evidence of any real imposition on the FDA from the operation of the Michigan statute.

The preemption issue herein is intertwined with whether the fraud-on-the-FDA exception is severable from the statutory grant of immunity for FDA-approved drugs, a state law question on which the Michigan Supreme Court has not yet ruled. Application of established Michigan caselaw indicates that the exception is not properly severable, so that the statute must be considered as a whole in addressing preemption.

The Second Circuit properly distinguished *Buckman* on the grounds that the present case involves (i) state regulation of tort law affecting health and safety, as to which the presumption against preemption applies (rather than an attempted use of state law to police fraud on the FDA); (ii) alleged violation of state common law duties, rather than solely the federal duty of candor to the FDA; and (iii) invocation of fraud on the FDA to rebut an affirmative defense, rather than as an element of a claim.

ARGUMENT

1. The Second Circuit's preservation of drug product liability claims in Michigan will not have far-reaching effects.

The present case concerns a Michigan law which provides for a complete defense from product liability for the sale of FDA-approved drugs in Michigan. Its reach is quite limited: the Second Circuit's decision herein will directly affect only drug liability cases (1) brought in a federal court in the Second Circuit, (2) where Michigan law applies, and (3) where the plaintiff can prevail on a fraud-on-the-FDA defense to the statutory immunity. Such cases are likely to be rare.

Indeed, the issue presented herein may vanish entirely, as the Michigan legislature is currently considering repeal of the very statute at issue. **A bill to strike M.C.L. § 600.2946(5) has passed the Michigan House of Representatives, and is pending in the Senate,** where it has been referred to the Judiciary Committee.[1]

Assuming the act remains in effect, the fraud-on-the-FDA exception in the Michigan statute will only come into play when a Michigan resident who claims to be injured by an FDA-approved drug learns of adverse trial results that were withheld from the FDA. As a practical matter, plaintiffs will be unable to make a colorable claim of fraud-on-the-FDA in run-of-the-mill cases,[2] and the issue will

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[1] *See* Michigan House Bill 4044 (2007), reproduced on the Michigan Legislature's website at http://www.legislature.mi.gov/documents/2007-2008/billengrossed/House/htm/2007-HEBH-4044.htm.

[2] Thus, for example, the plaintiffs in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965-66 (6th Cir. 2004), one of the very few reported cases decided under M.C.L. § 600.2946(5), "had offered no

(Continued on following page)

likely be limited to groups of cases where widespread problems lead to withdrawal from the market of a popular drug such as Rezulin or Vioxx, with attendant publicity.

Even in cases in which the fraud-on-the-FDA exception is asserted, the potential for interference with the FDA's federal functions is more theoretical than real. The FDA can avoid being "dragged into" the dispute by "declin[ing] to permit its employees to testify about their official duties, pursuant to 21 C.F.R. § 20.1." Petition at 25.[3] As to the Petition's professed concern that absent FDA testimony, juries might speculate about how the FDA would have reacted to additional information, *see* Petition at 25, it is not apparent how such speculation, even if ill-informed, could hurt the FDA or its regulatory processes.

Moreover, as the Second Circuit pointed out, the potential burdens on the FDA from a fraud-on-the-FDA exception to statutory immunity for FDA-approved drugs are not materially different than the potential burdens from the residual common law rule under which such matters are admissible but not necessarily determinative. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 (2d Cir. 2007), App. 25a. Indeed, the formulation adopted by the Sixth Circuit in *Garcia*, requiring a finding of fraud by the FDA as a prerequisite to maintaining a product

---

proof of fraud" and "did not seek to satisfy the statutory exception". Petition at 18.

[3] Petitioners object that "courts do not always honor FDA's decisions in this regard", citing a district court decision denying an FDA motion to quash a subpoena. Petition at 25. However, this seems more like a reason to review that district court's discovery ruling than to review the Second Circuit's preemption decision herein.

liability action under the Michigan statute,[4] creates a potential for far greater burdens on the FDA. Rather than merely having the information submitted to it and its decision-making thereon reviewed by a court, the FDA could be saddled with the task of adjudicating fraud claims pursuant to citizen petitions in every civil case to which the Michigan act applies, whereupon the FDA would be required in each case to keep a formal record, furnish a response within 180 days, decide upon further petitions for reconsideration or stay, and ultimately face court review under the Administrative Procedure Act. *See* 21 C.F.R. § 10.30, App. 131a-137a. In effect, the position urged by Petitioner could make the FDA decide parties' dispute as to fraud, rather than leaving such private disputes to the court system.

Petitioners have made no showing that the issues implicated by M.C.L. § 600.2946(5), or by the differing preemption analyses of the Second and Sixth Circuits, will have any real or substantial disruptive effect on the FDA or the courts. If such issues become burdensome in fact, there will *ipso facto* be further opportunities for this Court to review them. As matters stand now, however, this case is unworthy of a grant of *certiorari*.

2. The exception for fraud on the FDA is not severable from the presumption of non-defectiveness for FDA-approved drugs.

A full analysis of the preemption issue herein is inextricably intertwined with consideration of whether the fraud-on-the-FDA exception is severable from the grant of

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[4] *See Garcia*, 385 F.3d at 966.

immunity for FDA-approved drugs – which is a question of Michigan law on which the Michigan Supreme Court has not spoken.

The difference between the approaches of the Second Circuit herein and the Sixth Circuit in *Garcia* turns on the courts' respective characterizations of the potentially preempted state law provision. The Sixth Circuit considered whether Michigan's fraud-on-the-FDA exception to statutory immunity, standing alone, is preempted, while the Second Circuit considered whether Respondents' "common law claims – preserved by Michigan's exception" are preempted. *Compare Garcia*, 385 F.3d at 965-66, *with*, *Desiano*, 467 F.3d at 89, App. 9a.[5] Determination of which characterization is appropriate requires consideration of whether the exception is severable from the non-liability provision. If the exception is bound up with the grant of immunity, so that M.C.L. § 600.2946(5) must be considered as a whole, then the statute is manifestly within the core of traditional state law authority over health and safety. *See* M.C.L. § 600.2946(5) (providing that FDA-approved drug is "not defective or unreasonably dangerous"). *Cf. Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 134 (Mich. 2003) (explaining that M.C.L. § 600.2946(5) directs courts to adopt "the FDA conclusion regarding the safety and efficacy of a drug").

Under a proper application of Michigan law, the fraud-on-the-FDA exception is not severable from the grant of

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[5] *See also, e.g.*, *Desiano*, 467 F.3d at 87, App. 4a ("The question presented by this appeal is whether . . . federal law also preempts traditional common law claims that survive a state's legislative narrowing of common law liability through a fraud exception to that statutory limitation.").

immunity for FDA-approved drugs. Consequently, a preemption analysis should consider the statute as a whole, and the Second Circuit was therefore correct in applying a presumption against preemption.

The *Garcia* court's holding that the exception for fraud on the FDA is severable from the remainder of M.C.L. § 600.2946(5) – which provides that an FDA-approved drug is not defective or unreasonably dangerous and that a manufacturer or seller of such a drug is generally not liable in a product liability action – was based upon a superficial and erroneous analysis. The sole Michigan authorities relied on in *Garcia* are a statute generally declaring acts to be severable (M.C.L. § 8.5) and a 1971 case described as "upholding the remainder of the enacted law because it is 'otherwise complete in itself and capable of being carried out without reference to the unconstitutional' section". *Garcia*, 385 F.3d at 967, quoting *Maki v. East Tawas*, 188 N.W.2d 593, 596 (Mich. 1971). However, the severability statute is expressly limited to remaining portions of the act "which can be given effect without the invalid portion", and "are not determined by the court to be inoperable". M.C.L. § 8.5.[6] Here, longstanding

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[6] MCL § 8.5 provides:

> In the construction of the statutes of this state the following rules shall be observed, unless such construction would be inconsistent with the manifest intent of the legislature, that is to say:
>
> If any portion of an act or the application thereof to any person or circumstances shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application, provided such remaining portions are not determined by the court to be inoperable, and to this end acts are declared to be severable.

principles of Michigan law, as well as basic fairness, require that the grant of non-liability for sale of FDA-approved drugs cannot be given effect, and must be found inoperable, in the absence of the exception which is part and parcel of the grant.

The *Garcia* opinion held that the exception in M.C.L. § 600.2946(5) is not preempted in all possible applications, but remains valid in cases where "the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Garcia*, 385 F.3d at 966 (italics in original). The opinion proceeded to decide that the Michigan legislature would prefer "immunity absent a finding of bribery or fraud by the Federal Government" to "no immunity" for FDA-approved drugs. *Id.* at 967. Far from being supported by Michigan caselaw, the *Garcia* court's method of proceeding is actually expressly disapproved in *Maki*, the sole Michigan case relied upon.

Maki involved a grant of governmental immunity from tort liability. Although *Maki* did indeed hold that other sections of the same act were severable, upon determining that the broad grant of immunity for all torts could not be upheld, it declined to preserve the constitutionality of the section in question by limiting it to immunity for negligence, reasoning that to do so "would require this Court to engage in judicial legislation." 188 N.W.2d at 595. According to *Maki*, the duty of the courts "is to construe what [the legislature] has written. After all, [the legislature] expresses its purpose by words. It is for us to ascertain – neither to add nor to subtract, neither to delete nor to distort." *Id.* at 596, quoting *Cases of Jam v. United States*, 340 U.S. 593, 596 (1951). Thus, the *Maki* court refused to engage in the process followed by the Sixth Circuit in *Garcia*. Rather than speculating about which

course the Michigan legislature would "rather" between two alternatives that were not before it, the *Maki* court simply observed that "[w]e cannot say that the legislature clearly understood" the issue before the court, and "we cannot determine how they would have voted had they known". The same is plainly true here.

Rather than speculating as to how the Michigan legislature would prefer the courts to rewrite the statute, courts should instead limit their inquiry into whether the remaining portions of the statute as written truly stand alone, or are intertwined with the invalid portion. Under Michigan law,

> To be capable of separate enforcement, the valid portion of the statute must be independent of the invalid sections, forming a complete act within itself. After separation of the valid parts of the enactment, the law enforced must be reasonable in view of the act as originally drafted.

Pletz v. Secretary of State, 336 N.W.2d 789, 809 (Mich. App. 1983) (footnotes omitted). As explained in a leading Michigan case:

> Whether the other parts of the statute must also be adjudged void because of the association must depend upon a consideration of the object of the law, and in what manner and to what extent the unconstitutional portion affects the remainder. . . . Where, therefore, a part of a statute is unconstitutional, that fact does not authorize the courts to declare the remainder void also, unless all the provisions are connected in subject matter, depending on each other, operating together for the same purpose, or otherwise so connected together in meaning, that it cannot be presumed the legislature would have passed the

> one without the other.... The point is ... whether they are essentially and inseparably connected in substance.... [I]f they are so mutually connected with and dependent on each other, as conditions, considerations, or compensations for each other, as to warrant the belief that the legislature intended them as a whole, and if all could not be carried into effect the legislature would not pass the residue independently, then if some parts are unconstitutional, all the provisions which are thus dependent, conditional, or connected must fall with them.

People v. McMurchy, 228 N.W. 723, 727 (Mich. 1930) (emphasis added; internal quotation marks and citation omitted). *See also Seals v. Henry Ford Hospital*, 333 N.W.2d 272 (Mich. App. 1983) (quoting part of foregoing passage from *McMurchy*).

In the present cases, it is clear that the fraud-on-the-FDA exception in M.C.L. § 600.2946(5) "affects", "depends upon", and is "essentially and inseparably connected" to the subject of the remainder, so that it cannot be excised without detracting from the apparent legislative intent. Subsection (5) has a single object – viz, the creation of a specific rebuttable presumption – which requires both the non-liability and the exception to operate as intended. The exception serves as a "condition, consideration or compensation" for the non-liability, and retaining the latter without the former would not be "reasonable in view of the act as originally drafted".

The Michigan legislature clearly intended that persons injured by FDA-approved drugs have a means to rebut the presumption that such drugs are not defective or unreasonably dangerous. Upon striking down the means of

rebuttal prescribed in the statute, the Sixth Circuit cavalierly substituted a different method with no showing of efficacy.[7] Long ago, the Michigan Supreme Court addressed a similar situation where the legislatively-prescribed means of rebutting a presumption was found to be invalid:

> The legislature, in making the rule that a deed recorded two years should be conclusive, did not design to leave parties without the means of testing it in the mean time. The remedy they provided was held void.... There is no other adequate remedy, and we think the whole statute was designed to go together; so that, the remedy failing, the whole provision falls with it.

Quinlon v. Rogers, 12 Mich. 168, 170 (1863). The same result should obtain here.

Notwithstanding the *Garcia* opinion's lack of grounding in Michigan caselaw, Petitioners contend that its interpretation of the Michigan statute is entitled to deference because Michigan is within the Sixth Circuit's

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[7] The inefficacy of the Sixth Circuit's formulation was recognized by the District Court herein:

> Now, there is no doubt that that outcome as a matter of social policy could perhaps be criticized by reasonable people. I assume ... that the FDA simply does not go around suing people or otherwise seeking to obtain or making findings that drug manufacturers have committed fraud in the new drug application process.
>
> The 6th Circuit's conclusion, therefore, puts plaintiffs who are subject to the Michigan statute in a pretty difficult spot. It may be that that is an undesirable outcome and it may well be that Congress and/or the Michigan legislature ought to address it....

App. 35a.

territory.[6] *See* Petition at 18-19 & n.9, citing *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981). That case recognized, however, that "[a] federal court in another circuit would be obliged to disregard a state law holding by the pertinent court of appeals if persuaded . . . that prior state court decisions had been inadvertently overlooked by the pertinent court of appeals." *Factors*, 652 F.2d at 283. Respondents submit that the Sixth Circuit in *Garcia* overlooked the Michigan caselaw directing that interconnected provisions may not be severed. Moreover, even if *Factors* would bind the Second Circuit, there is no principle requiring this Court to defer to the Sixth Circuit's flawed analysis, as Michigan is equally within the territory of this Court.

3. The Second Circuit's decision herein is not inconsistent with *Buckman*.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that an asserted state law cause of action for fraud on the FDA is impliedly preempted because it conflicts with the FDA's jurisdiction to police fraud against itself. *Buckman* involved an allegation that bone screws that were not unreasonably dangerous in themselves had been submitted to the FDA for approval based on inaccurate statements as to their intended use. Thus, the only duty claimed to have been breached was a federal duty to provide accurate information to the FDA,

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[6] *Garcia* was followed by the Michigan Court of Appeal in *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628515 (Mich. Ct. App. June 13, 2006), App. 213a. However, this unpublished *per curiam* opinion did not address severability.

rather than any general state law duty to refrain from marketing an unreasonably dangerous product.

The *Buckman* opinion distinguished *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), because the claims in *Buckman* were not grounded in the states' traditional regulation of product liability: "in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' *Medtronic, 518 U.S. at 485* – no presumption against pre-emption obtains in this case." *Buckman*, 531 U.S. at 348.[9] The *Buckman* opinion went on to emphasize the distinction between the claims therein based solely on violation of federal law, and claims based on state product liability law that also involve a violation of federal law:

> [I]t is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.

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[9] In *Medtronic*, this Court held that, in view of a strong presumption against federal preemption in areas of traditional local concern, state tort claims for injuries caused by FDA-approved medical devices are not generally preempted. *See Medtronic*, 518 U.S. at 475 (1996) (recognizing that public health and safety are "primarily, and historically, . . . matter[s] of local concern") (quoting *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985)) (ellipsis and brackets supplied by *Medtronic* opinion); *Id.* at 485 ("In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). *See also, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992) (construing preemption provisions "in light of the presumption against the pre-emption of state police power regulations").

> In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. . . . .
>
> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case.

Id. at 352-53 (citation omitted).

In the present case, the Second Circuit distinguished *Buckman* on three grounds. First, as to the presumption against preemption the court held:

> The Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to "regulat[e] matters of health and safety," which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest. As a result, while there may be reasons to override that presumption, the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*.

Desiano, 467 F.3d at 94, App. at 19a (citation omitted).

Second, the Second Circuit distinguished *Buckman* on the ground that the present case involves a claimed violation of traditional state common law tort duties, rather than solely the federal duty of candor to the FDA as in *Buckman*:

> These pre-existing common law claims survive under M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike

> the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA. Given *Buckman's* explanation of *Medtronic*, *Buckman* cannot be read as precluding such pre-existing common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA.

Desiano, 467 F.3d at 95, App. 21a-22a 9 (italics in original).

Third, the Second Circuit distinguished *Buckman* on the ground that in the present case fraud on the FDA serves only to rebut a statutory affirmative defense, rather than to supply an element of a claim. The court explained:

> Finding preemption of traditional common law claims where fraud is not even a required element – but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law – would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect.

Desiano, 467 F.3d at 96, App. 24a.

Each of these three distinctions is well grounded, and has not meaningfully been challenged by Petitioners in their present Petition for a writ of *certiorari*.

CONCLUSION

For the foregoing reasons, Petitioners' Petition for a writ of *certiorari* should be denied.

Respectfully submitted,

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Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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CORPORATE DISCLOSURE STATEMENT

Petitioners' Rule 29.6 Statements were set forth on page iv of their Petition, and there are no amendments to those statements.

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Respondents' brief does not challenge the sharp conflict between the decision of the Second Circuit below and that of the Sixth Circuit as to whether, under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), federal law preempts a state statutory requirement that—as a predicate to liability involving an FDA-approved prescription drug—the finder of fact must determine if there was fraud-on-the-FDA. Allowing such state law findings inevitably interferes with the federal agency's authority and its relationship with the entities that it regulates.

In order to obscure the far-reaching federal preemption issues flowing from the Second Circuit's overly narrow reading of *Buckman*, respondents assert that the issues here are limited to this particular case and the Michigan statute. However, the consequences of allowing state law determinations of fraud-on-the-FDA, which were central to *Buckman*, transcend this case and the Michigan statute for the following reasons, which respondents fail to address:

- There are seven comparable statutes enacted in other states, one of which in Texas makes a state law finding of fraud-on-the-FDA a predicate for liability and six of which require such a finding to award punitive damages.

- Thousands of pharmaceutical product liability cases pending in Multidistrict Litigations will be impacted by the precedential effect of the Second Circuit's holding that *Buckman*'s conflict preemption only applies to stand-alone claims based solely on fraud-on-the-FDA.

- The issues raised in the Petition impact litigation where fraud on federal agencies other than FDA is raised, as illustrated by a Ninth Circuit decision, which involved a claim requiring proof of fraud on the EPA,

and which conflicts with the Second Circuit opinion below.

Under the circumstances, the Petition presents an ideal vehicle for resolving the circuit conflict and clarifying the scope of *Buckman*. Michigan's broad statutory scheme, like that of seven other states, poses an even greater threat to the integrity of the federal regulatory system than the isolated, stand-alone, fraud-on-the-FDA claim at issue in *Buckman*.

I. The Conflict Among the Circuits and With *Buckman* Will Have Far-Reaching Effects.

Respondents urge that "this case is unlikely to have far-reaching effects." Brief in Opposition to Petition for a Writ of Certiorari ("Resp. Br.") at 1. That contention ignores the adverse consequences to the FDA's regulatory process and health care that will ensue when courts adopt the Second Circuit's overly restrictive interpretation of *Buckman*'s conflict preemption holding. The far-reaching effects of the issues raised by the Petition are twofold: (i) resolving the circuit split will impact many cases beyond this case and the Michigan statute; and (ii) a reasoned interpretation of *Buckman*, as in the Sixth Circuit's decision is essential to avert the dire consequences to the FDA regulatory process that *Buckman* found would result from allowing state law fraud-on-the-FDA claims. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004).

Respondents contend that the issue raised by the Petition "is limited to Michigan drug-injury cases brought within the Second Circuit in which a plaintiff can make a showing of fraud on the FDA." Resp. Br. at 1. That argument fails to recognize that the issue of whether under *Buckman*'s rationale there is preemption of state law requirements for determining fraud-on-the-FDA

could arise in any circuit in which a case is filed by a Michigan plaintiff or—as in the instant case—where there is a transfer pursuant to MDL procedures. *See* 28 U.S.C. § 1407.

Moreover, the scope of *Buckman's* conflict preemption rule has in fact arisen in a number of other jurisdictions, with inconsistent lower court decisions, where plaintiffs sued under one of the seven other state statutes with comparable fraud-on-the-FDA requirements as a predicate to liability or punitive damages. Petition for a Writ of Certiorari ("Pet.") at 11-12. The circuit conflict also will cause plaintiffs in Michigan and the seven other states to forum shop in order to take advantage of the Second Circuit's decision, rather than the law of the circuit in which plaintiffs reside and their alleged injuries occurred.

The conflict between the Second and Sixth Circuit's interpretation of *Buckman* also impacts thousands of other pharmaceutical product liability cases pending across the country where fraud-on-the-FDA is being litigated under state law in a variety of contexts. Brief of the Product Liability Advisory Council as *Amicus Curiae* in Support of Petitioner ("PLAC Br.") at 11-16. In addition, resolving the circuit conflict affects cases alleging fraud on agencies other than FDA. Thus, conflicting approaches to the *Buckman* preemption issue will continue to arise in cases such as the Ninth Circuit's decision in *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2001), which inconsistently with the rationale of the Second Circuit here, found preemption of a state law claim requiring a determination of fraud on the Environmental Protection Agency. Pet. at 9.

Respondents also assert that the Michigan legislature may consider further legislation on the subject, but that only shows that Michigan and other state legislatures

around the country need guidance now from this Court, in light of the circuit split, on how far they can go in imposing state law requirements on matters relating to fraud on federal regulatory agencies.

Respondents surmise that the impact of the Second Circuit's decision will be limited because "plaintiffs will be unable to make a colorable claim of fraud-on-the-FDA in run-of-the-mill cases, and the issue will likely be limited to groups of cases" such as those involving the drugs Rezulin or Vioxx. Resp. Br. at 2-3. As set forth in the Petition and the amicus briefs, numerous plaintiffs have made such colorable claims under state law, which are being actively litigated in state and federal courts. The Vioxx cases alleging fraud-on-the-FDA number in the thousands, as do Multidistrict Litigations involving other drugs and medical devices. PLAC Br. at 12-13.

Moreover, the threshold for plaintiffs to allege fraud-on-the-FDA is not high. A new drug application is a massive submission, and there are continuing submissions after approval. Pet. at 3; Brief for the Pharmaceutical Research and Manufactuers of America as *Amicus Curiae* Supporting Petitioners ("PhRMA Br.") at 11 n.3. In light of hindsight, plaintiffs can easily assert that some piece of information was omitted or should have been stated differently in submissions to FDA before or after drug approval. Any such simple allegation will launch the case down the path that *Buckman* has proscribed in order to protect the integrity of the FDA's regulatory function. Under the Second Circuit's holding, any case in which such allegations are made, other than in the context of a stand alone fraud-on-the-FDA claim, must proceed through discovery to the point where a fact-finder will have to determine under state law whether the defendant committed fraud-on-the-FDA.

In addition to the numerous cases that are affected by the circuit split, the Second Circuit's decision threatens to unleash the untoward consequences from conflicts with the FDA regulatory process that this Court in *Buckman* sought to avert. Thus, the Second Circuit's decision now provides a road map for plaintiffs to evade *Buckman's* preemption ruling simply by pleading their state-law allegations of fraud-on-the-FDA so that the claims are not "solely" based on such fraud. Further exacerbating the impact of the Second Circuit's ruling is its invitation to state legislatures and courts to enact and enforce legislation that makes a state law determination of fraud-on-the-FDA a prerequisite to liability or punitive damages recovery.

In sum, the Petition and the amicus briefs provide overwhelming support for the widespread impact of the Second Circuit's overly narrow interpretation of *Buckman* and the conflict with the Sixth Circuit as well as with the Ninth Circuit and numerous lower court decisions addressing state law requirements of proof of fraud-on-the-FDA and other federal regulatory agencies.

II. No "Showing", Beyond the Findings in *Buckman*, Is Necessary to Conclude That State Law Requirements to Determine Fraud-on-the-FDA Will Conflict with the Federal Regulatory System.

Respondents argue that "Petitioners have made no showing" that the issues implicated by the Michigan statute will have any disruptive effect on FDA. Resp. Br. at 4. To the contrary, that "showing" derives from *Buckman*'s conclusions that state law decisions on fraud-on-the-FDA inevitably conflict with the federal regulatory regime. No further showing is required to conclude that the FDA is entrusted by Congress with exclusive author-

ity to police fraud on the agency, and that state law determinations of fraud-on-the-FDA would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 349-350. As *Buckman* established, state law litigation of the issue of fraud-on-the-FDA undermines the "flexibility" that is "a critical component" of FDA's ability, entrusted to it by Congress, to "pursue[ ] difficult (and often competing) objectives" on complex scientific and medical issues relating to the safety and efficacy of drugs and medical devices. *Id.* at 349.

Respondents assert that "it is not apparent" how the FDA or its regulatory processes would be hurt by state juries' "ill-informed" speculation as to how FDA would react to certain information. Resp. Br. at 3. In so arguing, respondents fail to recognize that *Buckman* has identified the adverse impact that such "ill-informed" speculation would have on the integrity of FDA regulation. For example, it was apparent to this Court that in order to protect themselves from what states might require to avoid fraud-on-the-FDA, applicants would have "an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." 531 U.S. at 351. The same concerns could delay or deter applications for new drugs and devices to the detriment of health care. *Id.*

Respondents also cite to the Second Circuit's conclusion that the inducement to overburden the FDA with excessive data to satisfy state law requirements could also occur where "a court or jury is *allowed to consider* evidence of fraud against the FDA . . . ." App. 25a (emphasis in original) cited in Resp. Br. at 3. Respondents have added a gloss omitted from the Second Cir-

cuit's formulation to the effect that under the common law rule, "such matters are admissible *but not necessarily determinative*." Resp. Br. at 3 (emphasis added). *See* Pet. at 22-23. That is not the case with the Michigan statute and comparable statutes in seven other states, which require a determination under state law that fraud-on-the-FDA occurred. In that circumstance, the consequences to the regulatory process set forth in *Buckman* would likely occur. Under the reasoning of this Court, statutes requiring such determinations "conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348.

Respondents also assert that a preemption ruling under which only the FDA can determine if there was fraud on the agency would impose greater burdens on the FDA than allowing state courts to share that responsibility. Resp. Br. at 4. Congress has mandated the FDA's exclusive authority to police fraud on the agency and to allow citizens to file petitions bringing such fraud allegations to the FDA's attention. *Buckman*, 531 U.S. at 349. Any burdens on the FDA that this authority entails were contemplated by Congress. But, as *Buckman* held, preemption is warranted where conflicting duties would result from requiring applicants to "comply[ ] with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes." *Id.* at 350.

III. The Preemption Issues Raised by this Petition Are Not Dependent on State Law.

Respondents argue that the preemption issues raised by this Petition are "inextricably intertwined with consideration of whether the fraud-on-the-FDA exception is severable from the" remainder of the Michigan tort reform statute, which is governed by Michigan law. Resp. Br. at 4-5. This argument puts the cart before the

horse. The Michigan statute precludes liability for alleged injury from FDA-approved prescription drugs, with an exception where there is a state law finding of fraud-on-the-FDA. The question of whether the exception is severable from the remainder of the statute is not reached unless the exception's requirement to prove fraud-on-the-FDA is first held to be preempted.

Michigan law regarding severance has nothing to do with the conflict between the Sixth Circuit and the Second Circuit. Rather, the circuits differed in their interpretation of the scope of preemption under *Buckman*, particularly whether—as the Second Circuit held—*Buckman* is narrowly limited to stand-alone fraud-on-the-FDA claims, or whether—as the Sixth Circuit recognized—the consequences of state law fraud-on-the-FDA determinations are the same irrespective of the formal procedural context in which state courts are required to make that determination.

Accordingly, resolution of the issues raised by the Petition is not dependent on whether the Second Circuit properly deferred to the Sixth Circuit's construction of Michigan law,[1] or whether the Sixth Circuit properly applied Michigan law to sever the preempted portion of the state statute. This Court is not being asked to rule on any Michigan state law issues.

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[1] Even the Second Circuit did not premise its interpretation of *Buckman* on the argument respondents make here. Rather, citing *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981), it accepted the Sixth Circuit's ruling on Michigan law regarding severance. App. 14a; *see MacGregor v. State Mut. Life Assurance Co. of Worcester, Mass.*, 315 U.S. 280, 281 (1942) (per curiam) (accepting interpretation of Michigan law by Sixth Circuit).

IV. The Second Circuit's Decision Below Squarely Conflicts with *Buckman*.

Respondents quote *Buckman* to the effect that "the existence of these federal enactments [relating to FDA regulation] is a critical element in their [plaintiffs'] case." Resp. Br. at 13 quoting *Buckman*, 531 U.S. at 352-53. The same is true of the Michigan statute at issue here. Respondents cannot proceed with their product liability claims involving the FDA-approved prescription drug Rezulin without proving under state law that there was fraud-on-the-FDA.

Contrary to respondents' assertion (Resp. Br. at 13-14), the Petition meaningfully challenges the three grounds on which the Second Circuit sought to distinguish *Buckman*. *See* Pet. at 19-26; *see also* PhRMA Br. at 3-11. First, the Second Circuit erred in applying a presumption against preemption. As *Buckman* explained, the presumption does not apply because policing fraud on a federal agency is not within the states' historical functions. *Buckman*, 531 U.S. at 347-48; Pet. at 19-20. Second, the decision below to limit *Buckman* to stand-alone claims based "solely" on fraud-on-the-FDA would provide an open door to avoiding the conflict preemption mandated by this Court, and lead to the adverse consequences described in *Buckman*. Pet. at 21-22. Third, by narrowly interpreting *Buckman* to apply only to affirmative claims in a complaint and not to state law requirements to determine fraud-on-the-FDA in other procedural contexts, the Second Circuit put form over substance and exposed the federal regulatory process to unacceptable interference in the ways that *Buckman* depicted. Pet. at 23-26.

In sum, the direct conflict between the Second and Sixth Circuit, which respondents have not challenged, should be resolved by a grant of certiorari. Otherwise,

the Second Circuit's holding will lead to the conflicts between state law and the FDA's regulatory process found by this Court in *Buckman*, which in turn will have serious and widespread consequences in other cases regarding other state statutes.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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WARNER-LAMBERT COMPANY LLC and PFIZER, INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTIONS PRESENTED

Michigan's product liability law provides a complete defense to pharmaceutical manufacturers who market their products in compliance with requirements imposed on them by the Food and Drug Administration ("FDA"). A proviso to that defense, however, permits it to be overcome if a product liability plaintiff proves that a manufacturer "withholds from or represents to [FDA] information concerning the drug that is required to be submitted under the federal food, drug and cosmetics act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5). This Court has previously held that a state common law action premised on "fraud on the FDA" allegations virtually identical to the Michigan proviso is constitutionally preempted. *Buckman Co. v. Plaintiffs Legal Comm.*, 531 U.S. 341 (2001). Nevertheless, the court below held, in direct conflict with an earlier Sixth Circuit ruling, that constitutional preemption did not foreclose litigation of such alleged "fraud on the FDA" under the Michigan statute when fraud was a necessary, but not sufficient, element of plaintiff's case. The question presented therefore is:

Whether a product liability remedy under state law requiring adjudication of "fraud on the FDA" as an element of plaintiff's case can withstand a preemption challenge under *Buckman v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001).

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. Member companies are the source of a majority of all new medicines that are discovered and marketed. New medicines accounted for 40% percent of the lifespan increase between 1986 and 2000. *See* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, 21 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003). In the past decade alone, PhRMA's members invested approximately $300 billion to develop new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2007* 42 (2007).

The New Drug Approval review process of the Federal Food and Drug Administration ("FDA") is thorough and comprehensive. Only one of every 10,000 potential medicines investigated by PhRMA's members makes it through the research and development pipeline and is approved for patient use by FDA. Winning FDA approval, on average, takes 15 years of research and development and "costs over $800 million." *See* PhRMA, *What Goes Into the Costs of Prescription Drugs . . . and Other Questions About Your Medicine* 10 (2005). Potential new medicines pass through a series of crucial, FDA-supervised, stages on their way from research laboratories to the pharmacy shelf. *See* 21 C.F.R. § 312 *et seq.* Moreover, FDA has essentially plenary regulatory authority over the

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1. Pursuant to Rule 37.1 of the Rules of the Supreme Court of the United States, Amicus states that no counsel for any party to this case authored this brief, in whole or in part, and no person or entity other than Amicus, its members, or its counsel, has made any monetary contribution to the preparation or submission of this brief. Amicus has sought and has obtained written consent from counsel to both parties to submit this amicus brief.

pharmaceutical industry, including not only initial drug approval, but labeling and advertising as well. FDA has the authority and the means to redress violations of the Federal Food Drug and Cosmetics Act ("FDCA"), including fraud on the agency. *See* 21 U.S.C. § 355.

PhRMA's members closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues. PhRMA has a particular interest in cases involving possible state law interference with the comprehensive public health regulatory regime for prescription drugs administered by the FDA. PhRMA supports and endorses this Court's safeguarding of the "inherently federal" relationship between FDA and pharmaceutical manufacturers against state law intrusion arising from alleged fraud on the FDA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). PhRMA is concerned that the Second Circuit's decision in this case, unless reviewed and reversed, would undermine this Court's decision in *Buckman* and conflict with the Sixth Circuit's more sound resolution of the same preemption issue in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004).

The Second Circuit's opinion would effectively require Michigan product liability plaintiffs to litigate the issue of "fraud on the FDA" under Michigan law. Such litigation by private parties under state law would oust FDA from the exclusive, discretionary enforcement role Congress conferred upon it under FDCA. Congress entrusted to FDA the sole responsibility to police fraud on the agency and provided FDA with the tools to set and patrol appropriate bounds on manufacturer disclosure. By allowing fraud on the FDA to be regulated under state law, the Second Circuit's decision will introduce unnecessary uncertainty into a field that demands regulatory stability. Fraud-on-the-FDA litigation, even apart from permitting burdensome and intrusive discovery, thus would force PhRMA members to flood FDA with unnecessary information to protect themselves against determinations that, in the view of state judges and juries, such information was required to be submitted to FDA and

would have influenced FDA's regulatory judgments. Most fundamentally, such litigation would encourage further state law encroachment on the federal regime with consequent overlapping and conflicting regulatory mandates that can deter the beneficial use of existing medicines and the development of new ones.

INTRODUCTION

The petition addresses a direct and acknowledged conflict between two federal courts of appeal on an important issue of federal preemption. Michigan's product liability law provides a complete defense to pharmaceutical manufacturers from liability for injuries caused by drug products distributed and labeled consistent with FDA regulatory approval. Mich. Comp. Laws § 600.2946(5). The law provides, however, that this statutory defense can be overcome if a plaintiff proves that the relevant FDA approval was fraudulently obtained. *Id.* § 600.2946(5)(a). Petitioner argued to the Second Circuit that this "exception" to the FDA compliance defense was preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), in which this Court held that state law "fraud-on-the-FDA" liability claims conflicted with FDCA and therefore were preempted. The Second Circuit, finding *Buckman* distinguishable from the present case for several reasons, rejected Petitioner's preemption claim. The ruling is incorrect.

The Second Circuit wrongly invoked a presumption against preemption—one that some courts have applied to traditional product liability claims—to tip the scales against preemption of litigating fraud on the FDA under Michigan law. There is good reason to conclude that the presumption against preemption is inapplicable to conflict preemption generally, and obstacle preemption in particular. *See, e.g., Pharm. Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1206 (11th Cir. 2002). Regardless, *Buckman* makes clear that any such presumption is inapplicable to fraud-on-the-FDA claims because of the "inherently federal" relationship between FDA and pharmaceutical manufacturers which "originates from, is governed by, and terminates according to federal law."

Buckman, 531 U.S. at 347. A presumption favoring preservation of historic state regulatory interests has no applicability to state superintendence of the relationship between a federal agency and the industry it regulates.

The Second Circuit also erred in ruling that, because Respondents' causes of action were not grounded exclusively on a fraud-on-the-FDA claims theory, *Buckman* did not control. The conflict in *Buckman* arose from the state's assertion of power to review the regularity of federal approval actions under state law. Just as in *Buckman*, liability under the Michigan statute in this case turns on Respondents' ability to prove as a matter of state law that FDA approval was obtained through fraud. This determination would require the same speculation and interference with FDA's regulatory objectives that led to the preemption ruling in *Buckman*. *See id.* at 354 (Stevens, J., concurring).

The Second Circuit ignored the practical difficulties arising from allowing state courts to litigate fraud-on-the-FDA that were central to this Court's decision in *Buckman*. Permitting this uniquely federal question to be litigated under state law would defeat the exclusive role Congress granted to FDA in policing fraud; indeed, all such issues should be raised directly to the agency that Congress charged with determining whether fraud had occurred in the federal approval process. Denying preemption thus could produce cases where FDA and state courts reach contrary determinations on the same question of fraud. This is an untenable result that would allow states to "second-guess[] the FDA's decisionmaking" and "overburden[] its personnel." *Id.* Moreover, increased pressure on the application process and state oversight of the FDA approval process would force drug manufacturers to adjust their behavior by flooding FDA with additional information the agency is unlikely to deem useful or necessary. *See id.* at 351. Such a regime would ultimately overwhelm FDA's resources and undermine the agency's ability to protect public health.

As the Second Circuit acknowledged, its decision stands in direct conflict with the Sixth Circuit's application of *Buckman* to the same Michigan statute. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). The Sixth Circuit correctly held that, although the fraud-on-the-FDA issue arose in a slightly different posture from *Buckman* under the Michigan statute, *Buckman* preempted litigation of fraud-on-the-FDA under state law and thus limited any application of fraud to cases where the federal authority had made its own prior fraud determination. As here, the *Garcia* plaintiff sought to prove under state law that fraud had occurred, and the court properly held that this claim was preempted under *Buckman*, requiring the plaintiff's underlying claim to be dismissed in accordance with the remaining provisions of Michigan law. *See id.* at 965.

The Court should resolve this square conflict. The issue of fraud-on-the-FDA not only arises under Michigan statutory law and an essentially identical Texas law, it controls whether punitive damages will be allowed against drug manufacturers in at least six other states. Evaluation of these statutes has produced decisions that support *Buckman* preemption and conflict with the decision below. *See, e.g., Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166 (D. Ariz. 2005); *Ledbetter v. Merck & Co.*, No. 05-59499, 2007 WL 1181991 (Tex. Dist. Ct. Harris County Apr. 19, 2007); *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266 (M.D. Tenn. Feb. 27, 2007).

Moreover, the impact of *Buckman* has spread well beyond the FDA arena. *See, e.g., Nathan Kimmel, Inc., v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Zwiercan v. Gen. Motors Corp.*, No. 3235 (June Term), 2002 WL 31053838 (Pa. Com. Pl. Sept. 11, 2002); *Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704 (E.D. Tenn. 2001). Reversing the decision below therefore would both settle the *Buckman* issue in the FDA context and strengthen the federal preemption that rightly protects federal agency actions from being second-guessed under state law in a variety of federal regulatory areas and in a large number of cases.

REASONS FOR GRANTING THE PETITION

I. Certiorari Should Be Granted To Resolve An Acknowledged Split Between The Courts Of Appeal Of The Second And Sixth Circuit On An Important Issue Of Federal Preemption.

The Second Circuit, in the case at bar, confronted a products liability claim against a pharmaceutical manufacturer under Michigan law. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 93 (2d Cir. 2006). Michigan law effectively allows pharmaceutical manufacturers a complete defense against product liability when their products are distributed in accordance with FDA regulatory requirements. *See* Mich. Comp. Laws § 600.2946(5). The statutory defense does not apply, however, where the manufacturer "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under [FDCA] and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted." *Id.* § 600.2946(5)(a).

The validity of this "fraud-on-the-FDA" exception to the Michigan statutory defense depends on the force and meaning of this Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the plaintiff brought a state law cause of action, which alleged that consultant to a medical device manufacturer had made "fraudulent representations" to FDA during the approval process. *See id.* at 343. According to the plaintiffs, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* at 344. This Court unanimously ruled that state law "fraud-on-the-FDA" product liability causes of action conflicted with, and "therefore [were] impliedly preempted by, federal law." *Id.* at 348; *id.* at 353 n.1 (Stevens, J., concurring) (agreeing that "federal law 'pre-empts' this state law fraud-on-the-FDA claim").

In this case, the Second Circuit rejected the applicability of *Buckman* and ruled that the exception to the Michigan statutory defense, which hinged on whether FDA had been defrauded in

the application process, was not preempted. *See Desiano*, 467 F.3d at 93 (finding a "meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law"). As explained below, the Second Circuit reached this result for three principal reasons that do not provide a sufficient basis for distinguishing *Buckman* from the present case.

First, the court found that, because the Michigan statute made fraud on the FDA an element of product liability claims, a presumption against preemption applied. *See id.* at 94 ("[T]he cause of action . . . cannot reasonably be characterized as a state's attempt to police fraud against the FDA . . . . The object of the legislative scheme was rather to regulate and restrict when victims could continue to recover under preexisting state products liability law."). At the outset, it remains unsettled whether the presumption against preemption even applies in the implied preemption context. *Compare Pharm. Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1206 (11th Cir. 2002) ("In this circuit, a state statute is generally not entitled to a presumption against implied conflict preemption."), *with Frank Bros, Inc. v. Wisconsin Dep't of Transp.*, 409 F.3d 880, 885 (7th Cir. 2005) ("We presume that, in all circumstances, Congress does not intend to supplant state law."). This Court has expressly acknowledged that whether the presumption applies in the context of implied conflict preemption remains an open question. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000) ("We leave for another day a consideration in this context of a presumption against preemption.").

In fact, there is good reason to conclude that the presumption is inapplicable to the obstacle preemption framework. As the Court has explained, artificially narrowing the reach of a federal statute, through the invocation of the presumption, makes little sense in such circumstances: "[O]ne can assume that Congress or an agency ordinarily would not intend to permit a significant conflict . . . . To insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking, would be in certain cases to tolerate conflicts that an agency,

and therefore Congress, is most unlikely to have intended." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000). A presumption that requires a *narrow* reading of a congressional enactment has no place in an examination of whether a state law imposes an obstacle to the accomplishment of federal objectives. *See id.* ("The dissent, as we have said, apparently welcomes that result, at least where 'frustration-of-purpos[e]' pre-emption by agency regulation is at issue. We do not." (internal citations omitted)).

In any event, the court's invocation of the presumption cannot be squared with *Buckman*. Whether the presumption applies cannot turn, as the Second Circuit would have it, on whether the "legislative scheme" generally seeks to police fraud against the FDA or whether the state law at issue vindicates some broader objective. Under such a view, states could make fraud on the agency a convenient tool for asserting power to set aside or ignore relevant federal requirements so long as a finding of irregularity was not the sole basis for liability under state law. *Buckman* is not so myopic. *See* Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. of Tort Law, Issue 1, Article 5 (2006) (criticizing *Desiano* for making "a huge deal out of the pedigree of the state law cause of action when the dominant concern of the Supreme Court was the entanglement of the FDA in state litigation, which remains the same no matter how state law tees up the plaintiff's cause of action").

Rather, *Buckman* makes clear that the presumption does not apply, not because fraud-on-the-FDA was the basis for liability, but because fraud-on-the-FDA litigation would allow state court judges and juries to invade and impose added and potentially inconsistent requirements on the relationship between FDA and drug manufacturers. *See Buckman*, 531 U.S. at 348 (explaining that the "conflict stems from the fact that the federal regulatory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate

balance of statutory objectives"). In short, "the relationship between a federal agency and the entity it regulates is *inherently federal in character* because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347 (emphasis added). Accordingly, the presumption does not apply in *any* case where state law permits the issue of fraud-on-the-FDA to be litigated. This is just such a case.

The Second Circuit's invocation of the presumption infected the court's mistaken ruling throughout. *See Desiano*, 467 F.3d at 95 & n.7 (framing its refusal to allow Congress "without any explicit expression of intent . . . to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers" as "another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case"); *see also id.* at 96 ("Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." (citations omitted)); *id.* at 98 ("The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims."). Correcting that error alone warrants a grant of certiorari to reverse the decision below.

Second, the court below claimed that, unlike in *Buckman*, the plaintiffs' causes of action were not grounded exclusively on a fraud-on-the-FDA theory. *See id.* at 95 (concluding that "unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA" and that "plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime"). This is an overly narrow reading of *Buckman*. Again, *Buckman* did not find preemption because the fraud-on-the-FDA determination was sufficient to obtain a judgment against the defendant. Rather, *Buckman* made clear that preemption followed from the necessity of proving fraud on the FDA as part of the case. Here, just as in *Buckman*, liability under the

Michigan statute turns on whether the plaintiff can establish that the defendants obtained FDA approval through fraud. *See id.* at 95. And, in both *Buckman* and the present case, that determination would require a speculative assessment as to whether FDA would have required the information at issue to have been submitted and whether FDA would have reached a different regulatory decision based on that information.

Hence, Michigan law fosters the very type of state interference that *Buckman* concluded was preempted under federal law. *See Buckman*, 531 U.S. at 352 ("[T]he existence of these federal enactments is a critical element in their case."); *id.* at 354 (Stevens, J., concurring) ("This would be a different case, if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market."). Indeed, the Second Circuit's interpretation of *Buckman* appears to allow a state judge or jury to find fraud on the FDA even where FDA had specifically ruled that no such fraud had occurred. *Compare Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 9 (Cal. 2004) (preempting state law cause of action where "FDA has rejected plaintiff's claim that his data justify a different warning, and defendants do not claim to have any additional data").[2] This cannot be correct: "Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply." *Ledbetter v. Merck & Co.*, No. 05-59499, 2007 WL 1181991 (Tex. Dist. Ct. Harris County Apr. 20, 2007); *see also* Epstein, *supra*, at 7 (explaining that *Buckman* "held unanimously . . . that no tort plaintiff could bring any tort action that made an evaluation of FDA conduct the subject of state court proceedings, with their extensive pre-trial discovery by way of both interrogatories and deposition").

2. In so doing, the Second Circuit's decision thus discourages citizen petitions to FDA, *see* 21 C.F.R. § 10.30, which unlike state law suits, allow the agency with the expertise and institutional knowledge to reach an informed decision about alleged fraud.

Third, the Second Circuit blatantly disregarded the practical effects of state court fraud-on-the-FDA litigation that drove this Court's decision in *Buckman*. *See Desiano*, 467 F.3d at 97. Fraud-on-the-FDA litigation under state law interferes with important federal policies and obstructs FDA's ability to fulfill its congressional mandate. Foremost, allowing state courts to pursue "fraud-on-the-FDA" questions undermines the enforcement flexibility Congress entrusted to FDA. *See Buckman*, 531 U.S. at 341-42. FDA has a variety of tools at its disposal to police fraud on the agency in the approval process. *See id.* at 349 (explaining that FDA is "empowered to investigate suspected fraud" and that federal law includes "various provisions aimed at detecting, deterring, and punishing false statements made during . . . approval processes"). In responding to fraud, FDA, may, in its unfettered discretion, seek injunctive relief, 21 U.S.C. § 332, civil penalties, *id.* § 333(g)(1)(A), or criminal prosecution, *id.* § 333(a). FDA may also seize a medical device, *id.* § 334(a)(2)(D), or have a prescription drug removed from the marketplace, *id.* § 334(a)(1). The availability of this range of regulatory options is central to FDA's mission: "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349.

State court fraud-on-the-FDA litigation also would undermine FDA's ability to make operative the scientific determinations that Congress entrusted to the agency.[3] In determining the scope of a manufacturer's required disclosures and how any item of information affects the ultimate determination whether a drug is safe and effective under labeled conditions of use, FDA exercises critical scientific judgment

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3. FDA's new drug approval ("NDA") process is extensive. *See* 21 U.S.C. § 355(b). The manufacturer must submit a litany of information and scientific data relating to the drug's safety and efficacy. *Id.* § 355(b)(1); 21 C.F.R. § 314.50 ("The application is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.").

taking into account the entire file and, often, the advice of expert advisory committees. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("Under the Act and FDA regulations, the agency makes approval decisions based . . . on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling." (citation omitted)). FDA has made this clear in congressional testimony:

> Every time the scientists on our staff allow a new drug to come on the market, they have to take the sum total of scientific knowledge that they can muster about the drug, and reach a conclusion as to whether or not the good that that drug will do, the lives it will save or the suffering that it will prevent, outweighs the known side effects.

Drug Industry Antitrust Act: Hearing Before the Antitrust Subcomm. on Antitrust, 87th Cong. 135 (1962).[4]

Indeed, FDA's scientific judgments warrant considerable deference. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973) ("The determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations" and is "peculiarly suited to initial determination by the FDA."); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1043 (10th Cir. 2006), *cert. denied*, 127 S. Ct. 2295 (2007) ("The review of scientific literature is properly in the province of the FDA, to which this Court grants deference based on its expertise."); *Schering Corp. v. FDA*, 51 F.3d 390, 399

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4. Juries thus would be forced to predict whether the information allegedly withheld during the NDA approval process was material to FDA's approval. Juries simply are not in a position to evaluate the scientific "materiality" of information not submitted to FDA. *Cf. Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir. 1995) ("Given the FDA's central role in reviewing and approving devices under the MDAs, the FDA is in the best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction.").

(3d Cir. 1995) ("[FDA's] judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us."). Yet, under the Second Circuit's decision, FDA decisions would be subject to limitless second-guessing from state judges and juries ill-equipped to make the scientific and technical judgments necessary to determine whether fraud was material. This burden would clearly obstruct FDA's execution of federal responsibilities under FDCA.

Finally, state superintendence over federal fraud claims would impose burdens on potential applicants and on FDA that directly contradict the expressed will of Congress. *See Buckman*, 531 U.S. at 350 ("[C]omplying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA."). That is, plaintiffs under state law will seek to expand the category of information "required to be submitted" to its outer limits. This necessarily will draw a reaction from drug manufacturers. *See id.* at 351 ("Applicants would . . . have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application."). Fraud-on-the-FDA claims would cause applicants "to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.*

FDA clearly would be overwhelmed if every piece of potential raw data or speculative theory related to a drug, a clinical trial, or an adverse drug event were reported to the agency. *See, e.g., Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) (observing that excessive risk-oriented regulation "can harm the public health . . . by encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments"). This Court therefore held that fraud-on-the-FDA claims "would exert an extraneous pull on the

scheme established by Congress, and it is therefore is pre-empted by that scheme." *Buckman*, 531 U.S. at 353. Under FDCA, responsibility rests with FDA-not the States-to balance the need to police fraud on the agency against the risk of excessive disclosures in drug approval applications. Allowing states to adjudicate fraud-on-the-FDA claims is incompatible with these uniquely federal objectives. For all these reasons, both legal and practical, the Second Circuit's decision to cabin *Buckman* to cases where the cause of action relies exclusively on fraud-on-the-FDA to impose liability under state law is erroneous.

Indeed, the Sixth Circuit, facing the same issue as the Second, correctly ruled that the Michigan fraud-on-the-FDA exception was preempted under *Buckman*. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). That court acknowledged that the Michigan law presented "a somewhat different legal regime from the one invalidated in *Buckman*." *Id.* at 965-66 (explaining that, under the Michigan law, the fraud-on-the-FDA question arose in the context of an exception to a defense, as opposed to "a specific cause of action for fraud on the FDA"). It nevertheless properly concluded that those differences were "immaterial" in that "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* at 966 (citations and quotations omitted).

The court focused its analysis on *state litigation* of fraud-on-the FDA claims at issue here. "Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch meddling concerns that animated *Buckman*." *Id.* (emphasis added). Accordingly, whether *Buckman* preempts the Michigan exception will turn on whether the "plaintiff asks a state court to find . . . fraud on the FDA". *Id.* Because, in *Garcia*, the plaintiff sought a finding from the court that fraud occurred-and "did not offer any federal findings"-the state law products liability claim was preempted under *Buckman*. *Id.*; *see also Henderson v. Merck & Co., Inc.*, No. 04-CV-05987, 2005 WL 2600220, at *11 (E.D. Pa. Oct.

11, 2005) ("This Court follows the holdings of *Buckman* and *Garcia* and finds that . . . [Sections] 600.2946(5)(a) and (b) are preempted by the FDCA in most situations.").[5]

* * *

Buckman, in PhRMA's view, stands for the proposition that state law liability against a pharmaceutical manufacturer may not be dependent on a finding of fraud-on-the-FDA at least where FDA has not first made a finding of fraud on the agency with respect to the specific conduct at issue in that case. There can be no dispute that a clean split of circuit court authority exists because the Sixth Circuit accepts that principle and the decision below rejected it. This Court should accept the petition for writ of certiorari and resolve the split in favor of the Sixth Circuit. FDA simply cannot properly function under a regime where it shares authority over fraud in the approval process, whether stated as a cause of action or an exception to state law immunity, with the judges and juries of fifty states.

II. The Dispute Over The Preemption Rationale Underlying *Buckman* Is Not Limited To The Michigan Immunity Provision Or Even FDA-Related Litigation.

The implications of the Second Circuit's misinterpretation of *Buckman* are too important to allow this decision to remain in place. At least one other state has enacted a law like the Michigan provision at issue here. *See, e.g.*, Tex. Civ. Prac. & Rem. Code Ann. § 82.007. Other states permit litigation of fraud on the FDA as a basis for punitive damages on the FDA.

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5. A different analysis might be required where FDA has conclusively ruled that fraud occurred in a particular case, so that parallel state law remedies might reinforce the federal requirement. Such suits might not raise the same legal and policy concerns that arise when lay judges and juries are allowed either to speculate as to whether FDA would have reached that conclusion or are allowed drag FDA into the litigation as a fact or expert witness. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005); *see also id.* at 455 (Breyer, J., concurring) (adding that "the federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements").

See, e.g., Ariz. Rev. Stat. § 12-701; N.D. Cent. Code § 32-03.2-11; N.J. Stat. Ann. § 2A:58C-5(c); Ohio Rev. Code Ann. § 30.027; Or. Rev. Stat. Ann. § 30.927; Utah Code Ann. § 78-18-2. Under both types of statutory regime, liability rises and falls with the plaintiff's ability to prove to a lay judge or jury that fraud on the FDA occurred.

The validity of these statutes, like the Michigan statute at issue in *Garcia* and *Desiano*, therefore inevitably turns on the meaning of *Buckman*. *See, e.g.*, *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1171-74 (D. Ariz. 2005) ("Both a common law fraud-on-the-FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process."); *Ledbetter*, 2007 WL 1181991, at *5-6 ("Given the extent of federal regulation, and the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas judge or jury to make the same inquiry would impinge on a uniquely federal issue."); *cf. In re Aredia & Zometa Prods. Liability Litig.*, No. 06-1760, 2007 WL 649266, at *9 (M.D. Tenn. Feb. 27, 2007) (explaining that "FDA will need to make a finding on the matter of fraud before the Plaintiffs will be entitled to recover punitive damages under New Jersey law").

Courts also have applied *Buckman* to common law claims based on fraud on the FDA. *See, e.g.*, *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001). In *Flynn*, the court held that, under *Buckman*, the FDCA impliedly preempted the plaintiff's state law fraud-on-the-FDA claim, which alleged that but for fraudulent misrepresentations made by Fen-phen's manufacturer during its approval process, the drug never would have been approved, and consequently, the plaintiff never would have been injured. *See id.* at 345. The court noted the similarities between the regulatory schemes that govern the approval of drugs and medical devices. *See id.* at 349. Because of these

similarities, subjecting drug manufacturers to the "50 States' tort regimes" would most likely have a disruptive effect on FDA's authority "to consistently police fraud within the agency's powers." *Id.* (citing *Buckman*, 531 U.S. at 348).

Moreover, a wealth of case law well beyond FDA-related litigation has built upon around *Buckman*. In *Nathan Kimmel, Inc., v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002), for example, the Ninth Circuit applied *Buckman* to a state suit claiming intentional interference with a prospective economic advantage. *Id.* at 1204-05. The basis of the state cause of action was that the defendant knowingly submitted false information to the EPA to obtain a particular label for a bag manufactured to contain an EPA-regulated pesticide. *Id.* Applying *Buckman*, the Ninth Circuit found that the plaintiff's state law claim was impliedly preempted by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 (1996). *Id.* at 1205.

As the Court explained, FIFRA is a "comprehensive regulatory scheme aimed at controlling the use, sale, and labeling of pesticides," and like FDA, EPA is empowered under the statute to deter and punish fraud using particular methods designed to "achieve a somewhat delicate balance of statutory objectives." *Id.* at 1203, 1206 (quoting *Buckman*, 531 U.S. at 348). The practical implications of allowing this suit to proceed would violate both the letter and the spirit of *Buckman*:

> [W]e are troubled that an applicant's disclosures under FIFRA, although not challenged by the EPA . . . may be judged illegal under state law. Such an approach would force FIFRA applicants to ensure that their disclosures to the EPA would satisfy not only standards imposed by that agency under federal law, but also the potentially heterogeneous standards propounded by each of the 50 states.

Id. at 1207.

Similarly, in *Zwiercan v. General Motors Corp.*, No. 02-3235, 2002 WL 31053838 (Pa. Com. Pl. Sept. 11, 2002), the plaintiff, after purchasing a car, brought an action against the car's manufacturer for breach of implied warranty and violation

of the Unfair Trade Practices and Consumer Protection Law ("UTPCPL") alleging the manufacturer's failure to disclose defective front seats in the vehicle. *See id.* at *1. The court found that a state-law claim that involved the UTPCPL was preempted under *Buckman*: "Defendant is correct in stating that in so far as Plaintiff's UTPCPL claim seeks redress for misstatements to the [National Highway Traffic Safety Administration], it is a 'fraud on the agency' claim, which is properly preempted by federal law." *Id.* at *6. Accordingly, "because the Plaintiff cannot use the UTPCPL to enforce an alleged fraud on a federal agency, Defendant's Motion for Summary Judgment on this issue is granted." *Id.*

Cases such as these are legion. *See, e.g., Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 722 (E.D. Tenn. 2001) (holding that, under *Buckman*, the comprehensive United States Department of Energy (DOE) regulations impliedly preempted the plaintiff's state law civil conspiracy claim, since allowing the claim to proceed would inevitably "conflict[ ] with the DOE's ability to set nuclear policy consistent with its own judgment and objectives"); *McCall v. Pacificare of Cal., Inc.*, 21 P.3d 1189, 1199 n.9 (2001) ("To the extent the [plaintiff's] complaint alleges fraud on the [Health Care Financing Administration], defendants may, on remand, assert it is preempted under the rule in *Buckman*."); *Andrx Pharms., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1369-70 (S.D. Fla. 2001) (holding that, under *Buckman*, the plaintiff's claims for deceptive and unfair practices, tortious interference with business relationships, and negligence per se were impliedly preempted by the Hatch-Waxman Act in the FDCA because all of these claims necessarily rely on violating the Act's patent listing requirements), *vacated on other grounds*, 276 F.3d 1368 (Fed. Cir. 2002); *Beck v. Koppers, Inc.*, Nos. 3:03CV60-P-D, 3:04CV160-P-D, 2006 WL 2228910, at *1 (N.D. Miss. Apr. 7, 2006) (rejecting state law fraud-on-the-EPA conspiracy claim because, "[g]iven the ruling in *Buckman*, the plaintiff may not recover for any alleged fraud against the [EPA] under the rubric of a state-law conspiracy claim").

Not all lower courts disagree, however, with the logic of *Desiano*. *See Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470

(Fed. Cir. 1998). In that case, the Federal Circuit confronted a state law unfair competition claim alleging that Exxon obtained a patent "by inequitable conduct" before the PTO. *Id.* at 1472. Exxon defended arguing that such a claim was preempted. *See id.* at 1473. The Federal Circuit rejected this argument, holding that the state law claim is not "preempted by the federal patent law, even if it requires the state court to adjudicate a question of federal patent law, provided the state law cause of action includes additional elements not found in the federal patent law cause of action and is not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law." *Id.*; *but see id.* at 1480 (Lourie, J., dissenting) ("Permitting a state law claim to be based essentially on an assertion of inequitable conduct . . . leads to the potential of conflicting results, an eventuality that preemption is intended to avoid.").

The court reached this conclusion notwithstanding a long line of authority sustaining federal exclusivity in the patent context. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964) (holding that the uniquely federal character of the patent system not only prevented states from encroaching upon it directly, but also prevented states "under some other law, such as that forbidding unfair competition, [from] giv[ing] protection of a kind that clashes with the objectives of the federal patent laws"); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1998) ("[O]ur past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."); *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1357 (Fed. Cir. 1991) (preempting a Michigan state tort action alleging "inequitable or other unsavory conduct of parties to proceedings in the Patent and Trademark Office" because "the PTO procedures themselves provided a remedy for Abbott's malfeasance").

As the Federal Circuit had explained in *Abbott Laboratories*, "[a]n additional state action would be an inappropriate collateral intrusion on the regulatory procedures

of the PTO, 'under the guise of a complaint sounding in tort' . . . and is contrary to Congress' preemptive regulation in the area of patent law." *Id.* at 1357 (quoting *Gilbert v. Ben-Asher*, 900 F.2d 1407, 1411 (1990)). The Federal Circuit's failure to adhere to *Stiffel* and *Bonito Boats*, and its own opinion in *Abbott Laboratories*, parallels the Second Circuit's failure to abide *Buckman*. Both decisions reward creative state legislatures with freedom to interfere in uniquely federal issues, such as patent and pharmaceutical regulation, that this Court has made clear should be free from state superintendence.

Accordingly, allowing the decision below to remain good law and provide a roadmap to evading *Buckman* will cast a shadow over an array of federal regulatory regimes. To the extent that the Second Circuit decision becomes precedential, a State need only enact a statute permitting liability to arise for federally-mandated actions, provide a defense negating that liability and include an exception for fraud on the federal agency to render *Buckman* a nullity. For example, Pennsylvania could simply enact statutory liability for defective automobile designs, create a National Highway Traffic Safety Administration compliance defense (to the extent that NHSTA has approved the design), but override the defense if approval were procured through fraud on the federal agency, and then argue that the *Zweircan* decision, *supra*, p. 10 should be set aside. *Buckman* would be a trivial addition to the law if stood for a proposition so narrow that states could avoid its mandate with such ease. Granting the petition, and reversing *Desiano* thus would not only resolve an issue important to pharmaceutical regulation, it would provide the Court an opportunity to more broadly set the course of the lower courts on this important aspect of federal preemption.

CONCLUSION

For all of the foregoing reasons, and for the reasons set forth in the petition, the Court should grant the petition on the question presented and reverse the decision of the United States Court of Appeals for the Second Circuit.

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No. 06-1498

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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

1. Whether, under the principles articulated in *Buckman Co. v. Plaintiffs' Legal Commission*, 531 U.S. 341 (2001), federal law preempts state law where it requires, as a precondition to the imposition of liability, that the fact-finder determine whether the defendant committed fraud against a federal agency—such that it affected the agency's product approval—although the agency has not found any fraud, and the state requirement would interfere with the agency's responsibilities.

2. Whether, under *Buckman*, federal law preempts the provision in a Michigan statute that requires the fact-finder, as a prerequisite to the imposition of liability, to determine whether a manufacturer of an FDA-approved drug committed fraud against the FDA—and, "but for" the fraud, the FDA would not have approved the drug—where the FDA, itself, has not found fraud on the Agency.

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INTEREST OF *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with more than 120 corporate members representing a broad cross-section of American and international manufacturers. These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective reflects the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 725 briefs as amicus curiae in both state and federal courts, including 66 in this Court, presenting the viewpoint of product manufacturers seeking fairness and balance in the application and development of the law.

PLAC has a significant interest in this case as the issue before the Court affects manufacturers in regulated industries, particularly pharmaceutical and medical device companies. Those effects, moreover, extend far beyond Michigan, for the question presented here regarding federal preemption may also be critical in tens of thousands of cases before state and federal courts. PLAC is well situated to address this question. The organization has filed *amicus* briefs in significant preemption cases, including *Wyeth v. Levine*, No. 2004-384, 2006 WL

1. The parties' letters consenting to the filing of this brief have been filed with the Clerk's office pursuant to this Court's Rule 37.3(a). Also, pursuant to Rule 37.6, *amicus* affirms that this brief was not authored in whole or in part by any party's counsel, nor did any person or entity other than PLAC or its counsel make a monetary contribution to the preparation or submission of this brief. A list of Corporate Members of PLAC is set forth in the Appendix.

3041078 (Vt. Oct. 27, 2006), *petition for cert. filed*, (U.S. Mar. 12, 2007) (No. 06-1249), *Buckman Co. v. Plaintiffs' Legal Commission*, 531 U.S. 341 (2001), *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Furthermore, the members of PLAC engage in commerce in all 50 states and the District of Columbia. They have faced the cross-pressures generated by divergent federal and state regulatory standards and common law rules. They have endured crushing burdens of litigation and borne liability merely for following the instructions of federal regulators. They understand—indeed, they have experienced—the practical consequences of state efforts to regulate the relationship of industries with their federal regulators. PLAC therefore can provide valuable insights on the issue before the Court.

STATEMENT

Respondents are citizens of Michigan. They sued Petitioners Warner-Lambert and Pfizer (collectively "Warner-Lambert") for injuries allegedly caused by Rezulin, a drug manufactured by Warner-Lambert and approved by the FDA for treatment of diabetes. Michigan law imposes liability on a manufacturer for injuries allegedly caused by an FDA-approved drug only if the manufacturer

> [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the federal, food, drug, and cosmetic act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

Mich. Comp. Laws § 600.2946 (5)(a) (2007) (citations omitted). Thus, in order to recover damages, respondents

needed to demonstrate that Warner-Lambert knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval or resulted in its removal from the market.

Warner-Lambert sought judgment on the pleadings because the inquiry into fraud on the FDA mandated by Michigan law invades the Agency's exclusive authority to police its relationship with regulated companies. In support of this position, Warner-Lambert relied on the Sixth Circuit's conclusion that, under *Buckman*, federal law preempts this inquiry except where the FDA itself has previously found fraud. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-966 (6th Cir. 2004). The district court agreed. It found that litigation regarding fraud on the FDA would interfere with the Agency's enforcement efforts. Petition for Writ of Certiorari app. at 35a-36a, *Warner-Lambert Co. LLC v. Kent*, No. 06-1498 (U.S. May 10, 2007). The Second Circuit reversed. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2007). Rejecting *Garcia*, the court held that *Buckman* would apply—and the predicted burdens on the FDA would occur—*only* where plaintiffs advanced a stand-alone cause of action for fraud on the Agency, not where the claim was "merely" an indispensable prerequisite to liability on another ground. *Id.* at 93-95.

SUMMARY OF THE ARGUMENT

The petition for certiorari frames a conflict between the Courts of Appeals for the Second and Sixth Circuits regarding the scope of preemption under *Buckman*. Specifically, the courts have disagreed on whether the FDA's regulation of drugs and medical devices preempts state tort claims predicated upon fraud on the FDA, or whether it preempts only stand-alone claims for such fraud. The Sixth Circuit in *Garcia* followed *Buckman* in ruling that the Michigan statute, which makes fraud against the FDA a prerequisite to liability for injuries caused by an FDA-approved product, would "inevitably conflict with the FDA's responsibility to police fraud." *Buckman*, 531 U.S. at 350; *see Garcia*, 385 F.3d at 966. The court therefore held that the statute is preempted except where the FDA itself has previously found a violation of its disclosure requirements, thereby obviating any inquiry on the subject in a tort case. *Garcia*, 385 F.3d at 966. The Second Circuit, addressing the same Michigan statute, came to the opposite conclusion. Misconstruing *Buckman*, the court rejected preemption because plaintiffs' claims were not *solely* for fraud on the FDA. *Desiano*, 467 F.3d at 93-95.

The impact of this conflict extends far beyond Michigan, and far beyond even the other seven states that similarly specify fraud on the FDA as a precondition of liability or punitive damages. Indeed, resolution of the issue before the Court will affect tens of thousands of cases seeking damages against drug and medical device manufacturers based on their dealings with the FDA. Ultimately, the proliferation of cases linking liability to the adequacy of companies' disclosures to the FDA could well upset the "somewhat delicate balance of statutory objectives" the FDA has struck in deterring and punishing fraud against the Agency. *Buckman*, 531 U.S. at 348. This Court should resolve the conflict now to avoid serious disruption and confusion.

ARGUMENT

I. The Court of Appeals' Formalistic Approach Nullifies the Key Inquiry as to Whether Claims for Fraud on the FDA Interfere with FDA Regulation

A. *Buckman* Focused on the Impact of Fraud on the FDA Claims

In *Buckman*, this Court addressed charges that a defendant had "made fraudulent representations to [the FDA] in the course of obtaining approval" to market a medical device and that "such representations were at least a 'but for' cause" of the plaintiffs' injuries. 531 U.S. at 343. At the outset of the opinion, the Court determined that no presumption against preemption applied. The Court reasoned that "policing fraud" against federal agencies was not traditionally the role of the states. *Id.* at 347. To the contrary, the Court found that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347. Thus, the plaintiffs could not claim the benefit of the presumption.

Having decided this procedural issue, the Court concluded that allegations of fraud on the FDA or violations of FDA disclosure requirements "conflict with, and are therefore impliedly preempted by, federal law." *Id.* at 348. In the Court's judgment, such claims can interfere with the Agency's determinations regarding the disclosures it wants, when it wants them, and which inducements and sanctions to apply to that end. Illustrating the scope and complexity of those determinations, the Court set forth the FDA's complex disclosure requirements applicable to medical devices, including the submission of prospective labeling and

advertisements, explanations and data regarding the similarities between a proposed device and existing devices, and any additional information the FDA seeks. *Id.* at 348-49. The requirements applicable in this case to prescription drugs are just as rigorous, if not more so. Before prescription drugs can be marketed, the sponsor must submit an extensive New Drug Application, including "full reports of investigations" into the safety and efficacy of the drug. 21 U.S.C. § 355(b)(1)(A) (2000). In addition, extensive and intricate regulations govern the reporting of adverse drug events that occur once the drug is on the market. *See* 21 C.F.R. § 314.80 (2002).

To enforce these disclosure requirements, as the Court noted in *Buckman*, the FDA has at its disposal provisions "aimed at detecting, deterring, and punishing false statements. . . ." 531 U.S. at 349. The FDA has the authority to investigate suspected fraud, 21 U.S.C. § 372 (2000), while citizens may report wrongdoing and petition the Agency to act, 21 C.F.R. § 10.30 (2002). The remedies available to the FDA include injunctive relief against fraud, 21 U.S.C. § 332 (2000), or seizure of the product, *id.* § 334. In addition, the Food, Drug, and Cosmetic Act ("FDCA") mandates that "failure to establish or maintain any record, or make any report, required" by these regulations is subject to criminal prosecution, *id.* §§ 331(e), 333(a), as are false statements to the Agency, 18 U.S.C. § 1001 (2000). In sum, the Court found, the "federal statutory scheme amply empowers the FDA to punish and deter fraud," and the FDA uses "this authority . . . to achieve a somewhat delicate balance of statutory objectives. The balance sought by the [Agency] can be skewed by allowing fraud-on-the-FDA claims under state tort law." 531 U.S. at 348.

In explaining how state litigation regarding fraud on the FDA could overrun the careful lines the FDA has drawn, the Court worried that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA or the MDA [, the Medical Device Amendments]." *Id.* at 350. Companies, the Court predicted, will fear that "their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351. That fear will fuel an "incentive to submit a deluge of information that the Administration neither wants nor needs."[2] *Id.*

B. The Court of Appeals Over-Emphasized the Procedural Format of Fraud on the FDA Claims

In reading *Buckman*, the Second Circuit appeared to fixate on this Court's observation that the plaintiffs there, in this Court's words, were not "relying on traditional state tort law which had predated the federal enactments in question," and that to the contrary, "the existence of these federal enactments [was] a critical element in their case." *Buckman*,

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2. For example, in 1997, the FDA stated that it did not wish to receive adverse event reports unless there was an identifiable patient and reporter, a suspect drug and an adverse event, "because reports without such information make interpretation of their significance difficult, at best, and impossible, in most instances." ADVERSE DRUG REACTION REPORTING REGULATIONS WORKING GROUP, GUIDANCE FOR INDUSTRY, POST-MARKETING ADVERSE EXPERIENCE REPORTING FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS: CLARIFICATION OF WHAT TO REPORT 3 (1997), http://www.fda.gov/cber/gdlns/advexp.pdf (last visited July 17, 2007). And the FDA has discouraged reporting of adverse events derived from "planned contacts and active solicitation" unless they are "serious" or "unexpected." *Id.* at 3-4.

531 U.S. at 353. The Court of Appeals thus distinguished *Buckman* on the ground that it involved a cause of action specifically for fraud on the FDA, while in this case the Michigan statute incorporates the fraud charge as a prerequisite to traditional tort liability. *See Desiano*, 467 F.3d at 94 ("M.C.L. § 2946(5) did not invent new causes of action premised on fraud against the FDA."). Elaborating on this distinction, the Court of Appeals found that the cause of action here "cannot reasonably be characterized as a state's *attempt* to police fraud against the FDA." *Id.* (emphasis added). Rather, the court held that the "*object* of the legislative scheme was ... to regulate and restrict when victims could continue to recover under preexisting state products liability law," *id.*, and that "the *goal* of preventing or punishing fraud against the FDA in [no] way *motivated* Michigan legislators," *id.* at 94 n.5 (emphasis added). The Court of Appeals therefore concluded that *Buckman* was inapplicable and the presumption against preemption, controlling. *Id.* at 98.

The Court of Appeals' distinction misgauges the focus of *Buckman*. To begin with, there is no hint in *Buckman*, nor in the long line of precedent on conflict preemption, that the presumption against preemption turns on a state's intent to regulate. Nor is there any suggestion that the question whether state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), depends on whether the state intended it to do so. As in prior preemption cases, the Court in *Buckman* was concerned about the effects of state law, not the intent behind it. To hold otherwise would mean that states could undermine federal regulation so long as they were merely negligent in doing so.

As to the traditional reach of tort claims, an embedded prerequisite of fraud on the FDA in a familiar cause of action, as in this case, is no more rooted in common law doctrine than the stand-alone claim in *Buckman*. The point of the discussion in *Buckman*, which the Court of Appeals missed, was that liability there did not hinge, as is normally the case, on the defendant's communications with the plaintiffs, their doctors or the public, but rather on the defendant's communications with the FDA. And whatever authority the state may have to regulate the relationship between pharmaceutical companies *and the public*, it cannot regulate the relationship between pharmaceutical companies *and the FDA*. The same principle applies here. Under the Michigan statute, liability hinges on Warner-Lambert's communications and relationship with the FDA, which the state may not regulate.

Furthermore, in shifting the focus from the impact of state law to the motivation behind it, from practical consequences to procedural formality, the Court of Appeals shortchanged this Court's concern that the burden of satisfying discordant common law duties and FDA requirements would lead applicants to inundate the Agency with unwanted and unhelpful information. *Buckman*, 531 U.S. at 351. To be sure, the Court of Appeals did touch on this concern. *Desiano*, 467 F.3d at 96-97. The court's logic in dismissing it, however, was both circular and empirically unfounded. The court inferred that pharmaceutical companies would continue to have incentives to flood the FDA with unwelcome disclosures so long as fact-finders in tort cases are allowed to consider evidence of fraud against the Agency and to react to that evidence in assessing liability and punitive damages. *Id.* at 97. Therefore, permitting plaintiffs to prove fraud on the FDA when rebutting a statutory defense to

liability would not, in the court's uncorroborated judgment, amplify those incentives. *Id.* Rather, the court inferred, only stand-alone claims of fraud against the FDA would markedly increase the incentives. *Id.* In other words, because "anything goes" short of a cause of action for fraud on the FDA, only the incremental impact of such a cause of action for fraud could have constitutional significance. But aside from the absence of any basis for confidence in the court's predictions, this argument simply assumes the answer to the question before the court—whether, in fact, "anything goes" short of a cause of action for fraud on the FDA.

Moreover, the Second Circuit's cramped focus on pleading invested the procedural context of *Buckman* with far more significance than this Court intended. *Buckman* addressed a cause of action for fraud on the FDA because that was the claim against the petitioner—who was a consultant, not a manufacturer.[3] Nevertheless, in discussing the potential impact of claims of fraud on the FDA, this Court explicitly addressed "applicants," that is manufacturers. *See Buckman*, 531 U.S. at 350. They—unlike consulting companies—get sued not only for fraud on the FDA, but routinely face claims of negligence, strict liability, fraud, and breach of warranty. Thus, under the reasoning of the court

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3. That *Buckman* involved a consultant, rather than a manufacturer, was happenstance. The trial court held that fraud on the FDA claims against medical device manufacturers were also preempted. *In re: Orthopedic Bone Screw Prods. Liab. Litig.*, No. MDL 1014, 1997 WL 305257, at *3 (E.D. Pa. March 28, 1997), *rev'd*, 159 F.3d 817 (3d Cir. 1998), *rev'd sub nom. Buckman Co. v. Plaintiffs' Legal Comm'n*, 531 U.S. 341 (2001). Because plaintiffs asserted no other cause of action against the consultant, they obtained an order under Fed. R. Civ. P. 54(b) permitting an interlocutory appeal only of the decision regarding the consultant.

below, in a multi-count complaint against a manufacturer, if a plaintiff alleges fraud on the FDA in a separate count, the claim would pose the threat that concerned this Court, skewing the "delicate balance of [the FDA's] statutory objectives," *id.* at 348, and thus would be preempted. But if the plaintiff inserted precisely the same allegations in the other counts for negligence or strict liability, they would not have the same effect and hence would not be preempted. Form is thus more important than substance. As this Court said many years ago in dismissing a comparably flawed argument, "To state the proposition is to refute it." *Howard* v. *Ill. Cent. R.R. Co.*, 207 U.S. 463, 502 (1908).

In short, the Sixth Circuit was correct in *Garcia* when it recognized that tort liability predicated on "*state court* findings of fraud on the FDA," will "raise the same inter-branch-meddling concerns that animated *Buckman.*" 385 F.3d at 966. Those concerns arise regardless of the procedural vehicle for those findings.

II. The Disposition of This Petition Could Affect Tens of Thousands of Cases

As the petition for certiorari demonstrates, cases interpreting *Buckman* have divided along the fault line reflected in *Desiano* and *Garcia.* Like the Second Circuit, a number of district courts and a state court have limited *Buckman* to stand-alone claims of fraud against the FDA. And like the Sixth Circuit, other federal district courts and state courts have assessed whether claims incorporating fraud on the FDA, whatever the procedural format, interfere with the Agency's mission and therefore are preempted. The petition for certiorari discusses these cases in detail.

Cataloging the cases on each side of the divide, however, only begins to convey the pervasiveness of this issue in product liability litigation involving drugs and medical devices, or the sheer number of cases affected. For instance, in the few weeks since the petition was filed, the New Jersey Superior Court handling the Vioxx litigation in that state ruled that federal law does not preempt the New Jersey statute allowing punitive damages only upon proof of fraud on the FDA. The court reasoned that *Buckman* did not apply because "the extensive regulations for medical devices *coupled with* the preemption provision of the MDA indicated sufficient intent of Congress to preempt fraud on the FDA claims." *Cona v. Merck & Co.*, No. ATL-L-3553-05 (N.J. Super. Ct. Law Div. June 8, 2007) (mem.). The absence of such an express preemption provision for prescription drugs, the court concluded, shows that Congress did not intend to permit implied preemption. *Id.* In fact, *Buckman* found implied preemption *despite* the presence of an express preemption provision in the MDA, not because of it. This Court stated that "neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" 531 U.S. at 352 (quoting *Geier v. Am. Honda Motor Co*, 529 U.S. 861, 869 (2000)). The New Jersey court's inverted reading of *Buckman* may affect the more than 15,000 cases pending before that court. *See Vioxx Case List*, http://www.judiciary.state.nj.us/mass-tort/vioxx/vioxxlist_022807.pdf.[4]

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4. Taking a different route toward the same destination, the MDL judge in *In re Vioxx Products Liability Litigation*, 401 F.Supp.2d 565, 593 (E.D. La. 2005), allowed plaintiffs to present "expert" testimony that Merck "was not forthcoming with the FDA with respect to the risks of *Vioxx*," in violation of FDA requirements. In the court's view, *Buckman* was inapplicable because plaintiffs did

(Cont'd)

By contrast, in the more than 1000 Vioxx cases consolidated in Texas state court, the trial judge reached the opposite conclusion regarding the Texas statute that makes fraud on the FDA a precondition to liability. *Ledbetter v. Merck & Co., Inc.*, Nos. 2005-59499, 2005-58543, 2007 WL 1181991 (Dist. Ct. Tex., 157th Jud. Dist. Apr. 19, 2007) (Trial Order); Heather Won Tesoriero, *Merck's Vioxx Troubles May Ebb with Ruling Poised to Aid Defense: Expected Case Dismissal Could Weaken Legal Basis for All 1,000 Texas Suits*, WALL ST. J., Apr. 13, 2007, at A3, *available at* http://online.wsj.com/article/SB117641547470168234.html. Thus, the vitality of many thousands of claims involving Vioxx depends in large measure on geography.

Likewise, geography appears determinative in litigation involving diet drugs. In *Bouchard v. American Home Products Corp.*, 213 F.Supp.2d 802, 812 (N.D. Ohio 2002), the court excluded evidence offered to show that the FDA was misled. *See also Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 349 (Minn. Ct. App. 2001). But in the MDL proceeding, *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001), the court held that an expert witness who was a former FDA employee could testify (a) "about the standard of care in the pharmaceutical industry regarding the manner in which certain information should

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(Cont'd)

not present causes of action for fraud on the FDA. *Id.* at 587, 595. The holding not only foretells the resolution of preemption motions regarding fraud on the FDA, but virtually guarantees that plaintiffs in the 8,800 cases before that court will invite juries to rely on this evidence. *See* Judicial Panel on Multidistrict Litigation, *Distribution of Pending MDL Dockets* (as of May 14, 2007), http://www.jpml.uscourts.gov/Pending_MDLs/PendingMDL-May-07.pdf [hereinafter "JPML Pending MDLs"] at 4.

be communicated to the FDA; and (b) what FDA officials would have done with certain additional information such as particular adverse event reports." *Id.* at *24. The ruling, if followed by remand courts after *Buckman*, would encourage juries in the 2533 diet drug cases pending in federal court to base liability on their assessment of the proper relationship between Wyeth and the FDA. *See* JPML Pending MDLs at 9.

The pressing need for this Court's guidance stems not only from the cases where courts have already addressed the scope of *Buckman*, but also from thousands of other cases where the issue is pending or necessarily will arise. These cases assert claims under the laws of virtually every state, not just Michigan. For instance, the master complaint in the multidistrict litigation involving the drug Propulsid alleges that, "Defendants failed to warn the FDA of material facts regarding the safety and efficacy of Propulsid, such that this drug would likely never have been approved, and no physician would have been able to prescribe this drug, for use in the United States." Master Class Action Complaint, *In re Propulsid Prods. Liab. Litig.*, MDL No. 1355, 2001 WL 34562410 (E.D. La. Oct. 5, 2001). Consequently, resolution of the question whether plaintiffs can recover damages based in whole or part on fraud against the FDA may affect the outcome in the 362 cases before that MDL Court.[5] *See* JPML Pending MDLs at 4.

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5. Similarly, the Master Complaint in the MDL proceeding involving defibrillators manufactured by Guidant, Inc. alleges that "[w]hile Guidant had provided some information to the FDA, that information was incomplete and misleading and did not adequately disclose the Device defects. Guidant's flawed disclosures did not comply with FDA regulations and violated the conditions of approval

(Cont'd)

More deftly, in the multidistrict litigation involving the anti-psychotic drug Zyprexa, many complaints seek to exploit the formalistic line that the Second Circuit and other courts have drawn. These complaints, while alleging that the defendant Eli Lilly "withheld from and/or misrepresented to the [FDA] required information that was material and relevant to the performance of the product," profess that the plaintiffs do not "make a claim *as such* for 'fraud on the FDA,' but Plaintiffs do allege that these misrepresentations and/or concealment and/or omissions are a contributing, producing and/or proximate cause of Plaintiffs' injuries." *See, e.g.*, Plaintiffs' Original Complaint for Personal Injuries and Demand for Jury Trial ¶ 86, *Hanson v. Eli Lilly & Co.*, No. 1:06CV05275, 2007 WL 1143404 (E.D.N.Y. Mar. 22, 2007) (emphasis added). In other words, the plaintiffs do not assert a cause of action for fraud on the FDA but seek to recover damages for it anyway. There are 1786 cases pending in the Zyprexa multi-district proceeding. *See* JPML Pending MDLs at 7.

Despite their massive scale, these matters still represent only a small slice of the litigation affected by the issue before this Court. Of direct concern to this Court is *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006), *cert. granted*, (U.S. Jun. 25, 2007) (No. 06-179). This Court recently

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(Cont'd)

for the Devices." Plaintiffs' Master Complaint for Personal Injury, Economic Loss, Third Party Payor and Medicare Secondary Payor Act Claims, Including Class Actions Jury Demand ¶ 82, *In re: Guidant Defibrillators Prods. Liab. Litig.*, No. 05-md-1708, 2006 WL 3327027 (D. Minn. Apr. 24, 2006). Thus again, the question of whether plaintiffs can offer evidence that the FDA was defrauded may influence the resolution of the 1361 cases pending before that court. *See* JPML Pending MDLs at 5.

granted review to decide whether tort claims involving medical devices subject to premarket approval ("PMA") are expressly preempted if they seek to impose requirements different from or in addition to those dictated by the FDA. *Id.* But failure to resolve the issue in this petition could render whatever decision this Court might reach in *Riegel* virtually inoperative. The ruling in *In re Medtronic, Inc. Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886 (D. Minn. 2006), highlights the problem. The MDL court there, addressing the same issue presented in *Riegel*, rejected express preemption based largely on the plaintiffs' allegations that Medtronic had not been forthcoming when obtaining the FDA's approval of the PMA. *Id.* at 895. Aside from the effect on the 1042 cases pending in that proceeding, *see* JPML Pending MDLs at 5, the court's reasoning would make fraud on the FDA a reliable end run around the MDA's express preemption provision. Plaintiffs will simply claim—on information and belief, no less—that in securing approval of the PMA, the manufacturer concealed the truth from the FDA, and that would be enough to allow a case to go forward.

Blazing such a facile path around the express preemption provision, moreover, would effectively nullify *Buckman* itself. Despite this Court's unanimous ruling, a claim of fraud on the FDA would become an essential element of plaintiffs' proof of liability in virtually every product liability case involving a PMA-approved device. Such a result would engender a far greater level of interference with the Agency than the intrusiveness the Court found so problematic in *Buckman*. In addition, if this approach infects pharmaceutical litigation, plaintiffs could potentially circumvent preemption even where the FDA ordered a manufacturer to do or say exactly what plaintiffs challenge. That question is at issue in more than 20 MDL proceedings, as well as many other state

and federal litigations, involving claims of injury from FDA-approved drugs. *See* Judicial Panel on Multidistrict Litigation, *Products Liability Litigations*, http://www.jpml.uscourts.gov/Pending_MDLs/Products_Liability/products_liability.html.

The FDA sought to block this end run when it promulgated its regulations on prescription drug labeling in 2006. In the preamble to the regulations, the Agency reaffirmed that "under existing preemption principles, FDA approval of labeling ... preempts conflicting or contrary State law." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). In providing examples of such conflicts, the FDA recognized that a company should not be able to procure an FDA decision by fraud and then assert that decision as a bar to state law claims. *Id.* at 3936. But consistent with *Buckman*, the FDA concluded that such considerations should limit preemption of conflicting state requirements *only* where the "*FDA has made a finding* that the sponsor withheld material information relating to the statement" at issue. *Id.* (emphasis added). To forsake that limitation would compound one type of intrusion—conflicts with FDA requirements—with another—disruption of the FDA's enforcement regime.

The point here is not that *Buckman* precludes any claim, argument or evidence regarding the basis for FDA decisions. Rather, it is that the Second Circuit's ruling *allows* virtually any collateral attack under state law on FDA determinations, provided the attack is encapsulated in a cause of action labeled as something other than a stand-alone fraud on the FDA claim. The ruling here is so expansive that it would leave *Buckman* inoperative in the many thousands of cases

where fraud on the FDA is at issue. It would potentially open a gaping loophole to the express preemption provision of the MDA—at issue in thousands more cases. And it would resurrect form pleading, where using (or avoiding) the right "magic words" potentially would moot the question whether states can impose liability on companies for obeying FDA instructions—implicated in thousands more litigations. Thus, failure to delineate the scope of *Buckman* now may result in untold numbers of cases being wrongly decided. When this Court ultimately does resolve the issue, the dislocation could be overwhelming, potentially necessitating reversals, retrials, and delays. In the meantime, as this Court predicted in *Buckman*, the multitude of assorted fraud on the FDA claims will disrupt the Agency's "measured approach" to enforcement and precipitate a flood of unsolicited information to the FDA, thereby interfering with the Agency's congressionally mandated responsibilities. This is exactly the result *Buckman* sought to avoid.

CONCLUSION

The Court of Appeals misread *Buckman*. That error, and the split in authority it reflects, is important to the courts, to industry, to federal regulators, and to litigants. This Court should resolve the issue now.

PLAC urges the Court to grant the petition for certiorari.

Respectfully submitted,

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APPENDIX

APPENDIX

Corporate Members of the Product Liability Advisory Council

as of 6/29/2007

3M
A.O. Smith Corporation
Altec Industries
Altria Corporate Services, Inc.
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies
Appleton Papers, Inc.
Arai Helmet, Ltd.
Astec Industries
BASF Corporation
Bayer Corporation
Bell Sports
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
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Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone Americas Holding, Inc.
Briggs & Stratton Corporation
Brown-Forman Corporation
CARQUEST Corporation
Caterpillar Inc.
Chevron Corporation

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Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation
DaimlerChrysler Corporation
The Dow Chemical Company
E & J Gallo Winery
E.I. DuPont De Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Ford Motor Company
Freightliner LLC
Genentech, Inc.
General Electric Company
General Motors Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
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Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jarden Corporation
Johnson & Johnson
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Joy Global Inc.,
Joy Mining Machinery Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Koch Industries
Kolcraft Enterprises, Inc.
Komatsu America Corp.
Kraft Foods North America, Inc.
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Magna International Inc.
Mazda (North America), Inc.
Medtronic, Inc.
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Mitsubishi Motors North America, Inc.
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Nokia Inc.
Novartis Consumer Health, Inc.
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Panasonic
Pfizer Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.
Purdue Pharma L.P.
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The Raymond Corporation
Raytheon Aircraft Company

Appendix

Remington Arms Company, Inc.
Rheem Manufacturing
RJ Reynolds Tobacco Company
Sanofi-Aventis
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
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Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
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Terex Corporation
Textron, Inc.
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
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Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
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Vulcan Materials Company
Watts Water Technologies, Inc.
Whirlpool Corporation
Wyeth
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.

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No. 06-1498

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER INC.,
Petitioners,
v.

KIMBERLY KENT, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

1. Whether, under the conflict preemption principles in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), federal law preempts state law to the extent that it requires the fact-finder to determine whether the defendant committed fraud on a federal agency that impacted the agency's product approval, where the agency – which is authorized by Congress to investigate and determine fraud – has not found any such fraud, and thus – as in *Buckman* – the state requirement would interfere with the agency's critical functions.

2. Whether, under the conflict preemption principles in *Buckman*, federal law preempts the provision in a Michigan statute that allows a product liability claim to be maintained against the manufacturer of an FDA-approved drug where, without an FDA finding of fraud on the agency, the fact-finder is required to make a finding under state law as to whether the manufacturer committed fraud-on-the-FDA and whether, in the absence of that fraud, the FDA would not have approved the drug.

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IN THE
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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government. To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke*, 529 U.S. 89 (2000).

WLF is particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that frustrates the objectives or operation of specific federal regulatory regimes, such as the Federal Food, Drug, and Cosmetic Act (FDCA) at issue here.

WLF also believes that medical consumers are best served by the widest possible dissemination of truthful information about FDA-approved products, even when that truthful information relates to off-label uses of the product. WLF successfully challenged, on First Amendment grounds, Food and Drug Administration (FDA) efforts to suppress dissemination of such information. *Washington Legal Found. v. Friedman*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF is concerned that if suits such as Respondents' are determined not to be preempted by federal law, manufacturers will be reluctant to employ methods permissible under federal law for disseminating such information, or even to seek FDA approval for drugs with potentially beneficial off-label uses.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing due solely to its interest in the important preemption issues raised by this case. WLF is filing this brief with the consent of all parties. The written consents have been lodged with the Clerk of the Court.

STATEMENT OF THE CASE

This case involves state-law personal injury suits filed by Respondents, several Michigan residents who claim to have suffered injury after having taken Rezulin, a prescription drug approved by FDA for treatment of diabetes. The suits were initially filed in state court in Michigan, were removed to federal district court by the defendants, and then were transferred to the U.S. District Court for the Southern District of New York pursuant to 28 U.S.C. § 1407 in connection with multidistrict litigation proceedings.

At issue is whether the federal law of preemption applies to a portion of a Michigan statute that the parties agree is applicable to the claims here. In 1995, Michigan adopted MCL § 600.2946(5), a statute that provides a prescription drug manufacturer or seller with "an *absolute defense* to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller." *Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 7 (2003) (emphasis added). The statute provides exceptions to that "absolute defense" in two limited situations: (a) if the defendant "intentionally withholds from or misrepresents to" FDA information concerning the drug that is required by federal law to be submitted to FDA *and*, had the information been accurately submitted, FDA would not have approved the drug or would have withdrawn approval; or (b) if the defendant "makes an illegal payment" to an FDA official for the purpose of securing or maintaining approval of the drug. MCL § 600.2946(5)(a) & (b).[2]

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[2] Respondents concede both that Rezulin was FDA-approved at all relevant times and that the drugs they took (and their labeling) were in compliance with FDA's approval at the time the drugs left the control

(continued...)

Petitioners Warner-Lambert Company LLC and Pfizer Inc. (hereinafter, collectively "Warner-Lambert") moved in the district court for judgment on the pleadings, contending that because Rezulin was an FDA-approved product, Respondents' claims were barred by MCL § 600.2946(5). Warner-Lambert asserted that Respondents could not seek to lift that bar by relying on the statute's fraud-on-the-FDA exception because that exception was preempted by federal law. The district court agreed, basing its preemption holding on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2000), and *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). Pet. App. 29a-38a.

The Second Circuit reversed. *Id.* 1a-28a. While recognizing that its decision directly conflicted with the Sixth Circuit's *Garcia* decision, the Second Circuit held that MCL § 600.2946(5)'s fraud-on-the-FDA exception was not preempted by federal law. The appeals court said that the Michigan statutory exception "d[id] not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman*," which the appeals court identified as the "impos[ition of] significant and distinctive burdens on the FDA and the entities it regulates." *Id.* 27a. The court also distinguished *Buckman* on the grounds that while *Buckman* had determined that "the presumption against preemption of a state law cause of action" did not apply in that case, *id.* 16a, the

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[2](...continued)
of Petitioners. Given that concession, it is of little moment – for purposes of determining the preemption issue raised herein – whether (as the Second Circuit contended, Pet. App. 23a-24a) the existence of FDA approval should be deemed an "affirmative defense," or whether the absence of FDA approval is a necessary element of Respondents' cause of action. Under either scenario, the bar against Petitioners' liability herein is "absolute" under Michigan law unless Respondents can come forward with evidence demonstrating fraud on the FDA.

presumption *did* apply to Respondents' claims because those claims sought to impose "traditional" common law liability and were not "an attempt to police fraud against the FDA." *Id.* 18a-19a. The appeals court said that a preemption finding would be tantamount to a holding that Congress had intended to "gut[] traditional state law duties between pharmaceutical companies and their consumers." *Id.* 20a. The court said that it was unwilling to ascribe such intent to Congress "[u]ntil and unless Congress states *explicitly* that it intends invalidation of state common law claims." *Id.* 24a (emphasis added).

Following the Second Circuit's denial of panel rehearing and rehearing *en banc*, *id.* 39a-40a, Warner-Lambert sought review in this Court.

REASONS FOR GRANTING THE PETITION

This case presents an issue of exceptional importance to pharmaceutical companies as well as to health care consumers throughout the country: is it an appropriate function of courts hearing state-law causes of action to impose liability based on their determinations regarding whether a pharmaceutical company defrauded the FDA for the purpose of obtaining FDA approval to market its product? This Court held in *Buckman* that state-law fraud-on-the-FDA claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives" and also "dramatically increase the burdens" facing companies applying for approval to market new drugs – and thus that Congress had impliedly preempted such claims when it established FDA's regulatory authority by enacting the FDCA. The issue here is whether those very same conflicts are an insufficient basis to find implied preemption when the state court second-guesses an FDA drug-approval decision not (as in *Buckman*) in connection with a fraud-on-the-FDA claim, but rather for the purpose of

determining a plaintiffs' entitlement to an exception from a state-created "absolute" bar to tort liability.

Review is warranted because the issues raised are of profound importance to health care in this country. The issues affect product liability litigation not only in Michigan but also in the many other States that have adopted tort reform laws similar to Michigan's in that they contain fraud-on-the-FDA exceptions to broad-based limitations on liability. If those exceptions are not deemed preempted, courts across the nation will be second-guessing FDA determinations that a drug is sufficiently safe and effective for its intended uses. That process will in turn create all the difficulties identified in *Buckman* as the basis for this Court's determination that fraud-on-the-FDA lawsuits are impliedly preempted by federal law – including, for example, a "skew[ing]" of the "somewhat delicate balance of statutory objectives" that FDA seeks to maintain. *Buckman*, 531 U.S. at 348. That process could also have a significant impact on the development of new, life-saving therapies. Review is warranted to determine whether Congress really intended to permit such impacts on the regulatory scheme it adopted. Moreover, so long as the issue remains unsettled, States interested in adopting tort reform legislation – and there is considerable evidence that many States have adopted, or are considering adopting, reform legislation designed to ensure that high litigation costs do not deter pharmaceutical companies from developing new, lifesaving therapies – will remain confused regarding how to do so in a manner that does not conflict with federal law.

Review is also warranted because the decision below directly and irreconcilably conflicts with the Sixth Circuit's decision in *Garcia*. Indeed, the Second Circuit made no effort to play down its fundamental disagreement with the Sixth Circuit on the scope of federal preemption. *See, e.g.*, Pet. App.

18a ("We disagree" with the Sixth Circuit's conclusion that there is "no meaningful difference" between *Buckman* and the preemption issue raised herein.) Although *Garcia* arose in a slightly different context – it was the *plaintiff* in *Garcia* who was arguing the most strenuously that Michigan's fraud-on-the-FDA exception was preempted by federal law – the precise issue raised by this Petition was decided in *Garcia* in a manner that is diametrically opposed to the decision below.

Review is also warranted because the decision below is so clearly at odds with *Buckman* and other decisions of this Court that have addressed federal preemption claims. The Second Circuit held that when a state-law tort action is designed to enforce the historic police powers of the State, Congress should *never* be deemed to have intended to preempt the action based solely on concerns that the court would be required to examine fraud-on-the-FDA issues, unless Congress has expressed that intent "explicitly." Pet. App. 24a. In so holding, the Second Circuit wrote off much of the doctrine of implied preemption in a manner that conflicts with numerous decisions of this Court.

Moreover, the Second Circuit badly misconstrued the presumption against preemption. The ultimate touchstone of preemption analysis is congressional intent; the "presumption against preemption" is merely an interpretive guide designed to assist the courts in discerning that intent. *Buckman* held that state-law fraud-on-the-FDA suits were impliedly preempted after identifying numerous ways in which judicial re-examination of fraud-on-the-FDA issues would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Once such "stand as an obstacle" findings have been made, a preemption determination is clearly mandated, and there is no need to resort to tie-breaking presumptions. The "presumption against preemption" cannot legitimately be invoked as a basis for ignoring this

Court's determination in *Buckman* that Congress's purposes and objectives would be frustrated by allowing the types of judicial inquiries that litigating MCL § 600.2946(5)'s fraud-on-the-FDA exception would entail.

I. REVIEW IS WARRANTED BECAUSE THE ISSUE AFFECTS TORT REFORM LAWS IN NUMEROUS STATES

Review is warranted because the issues raised are of profound importance to health care in this country. In recognition of the negative impact that excessive tort liability can have on the development of new, life-saving therapies, numerous States have adopted reform laws (such as the Michigan statute at issue here) designed to impose reasonable limits on such tort suits; many of the laws include fraud-on-the-FDA exceptions similar to the exception contained in MCL § 600.2946(5). Resolution of the issues raised herein will also resolve whether the fraud-on-the-FDA exceptions contained in those other state laws are similarly preempted.

Texas has adopted a statute that creates a rebuttable presumption of pharmaceutical company non-liability in product liability actions if the drug in question is labeled in compliance with FDA requirements. TEX. CIV. PRAC. & REM. CODE § 82.007(a). The presumption is inapplicable if the plaintiffs can demonstrate that the defendant obtained FDA approval for its drug by means of fraud on the FDA. *Id.*, § 82.007(b)(1). New Jersey has adopted a similar statute creating a rebuttable presumption that the warning on a drug or medical device is adequate if the warning was approved or prescribed by FDA. N.J. STAT. ANN. § 2A:58C-4. New Jersey goes further and prohibits an award of punitive damages in a case involving an approved drug or device, so long as the plaintiffs cannot

demonstrate that the defendant defrauded the FDA in order to win approval. N.J. STAT. ANN. § 2A:58C-5.

Five States have adopted limitations on punitive damages similar to New Jersey's. Each of those statutes includes an exception in cases in which plaintiffs can demonstrate that the drug company obtained product approval by defrauding FDA. *See* ARIZ. REV. STAT. § 12-701; N.D. CENT. CODE § 32-03.2-11(6), (7)(a); OHIO REV. CODE ANN. § 2307.80(C); OR. REV. STAT. § 30.927; UTAH CODE ANN. § 78-18-2. A decision in this case would determine the validity of the fraud-on-the-FDA exceptions contained in each of these seven statutes. As the Petition makes clear (Pet. 12-13 & n.7), whether the various fraud-on-the-FDA exceptions contained in these tort reform statutes are preempted by federal law is a frequently litigated issue, and courts have reached divergent results. Review is warranted to provide guidance to courts hearing preemption challenges to these fraud-on-the-FDA exceptions.

More broadly, health care experts throughout the country have increasingly come to recognize that health care suffers when product liability suits against pharmaceutical manufacturers proliferate too freely. As just one example, it is widely acknowledged that the on-going nationwide shortage of vaccines is in significant part attributable to vaccine manufacturers being driven from the market by high litigation costs. *See, e.g.*, General Accounting Office, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges* (Sept. 2002) (recent childhood vaccine shortages are at least partially attributable to liability concerns and litigation defense cost). The federal government has sought to ameliorate this litigation-driven problem by enacting legislation – the National Childhood Vaccine Act, 42 U.S.C. § 300aa-1 *et seq.* – protecting vaccine manufacturers from some of the costs of product liability litigation.

As the state statutes cited above indicate, numerous States are similarly interested in providing an appropriate balance between (on the one hand) protecting their citizens from injuries caused by the unreasonable conduct of product manufacturers and (on the other hand) protecting public health by ensuring that high litigation costs do not deter pharmaceutical manufacturers from continuing to develop and market new, lifesaving therapies.[3] Those States need guidance from the Court regarding how best to maintain that balance. Many States have opted to deter unreasonable pharmaceutical manufacturer conduct by including fraud-on-the-FDA exceptions in their tort reform legislation; review of this case is warranted to provide guidance from the Court regarding whether federal law permits adoption of such provisions.

II. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH OTHER FEDERAL APPELLATE DECISIONS

Review is also warranted because the decision below directly and irreconcilably conflicts with other federal appellate decisions, particularly the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). The Sixth

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[3] The business community is less willing to continue to spend the huge sums necessary to bring new pharmaceutical products to market in the face of an increasingly hostile litigation climate. Recent studies have concluded that the average cost of bringing new pharmaceutical products to market is as high as $1.7 billion. *See* Pharmacy Times, "Drug Development" (Dec. 2005) (available at http://www.pharmacytimes.com/Article.cfm?Menu=1&ID=2865). Tufts University pegs the average cost of developing a new biotechnology product at $1.2 billion. Tufts Center for the Study of Drug Development, *Average Cost to Develop a New Biotechnology Product Is $1.2 Billion* (Nov. 9, 2006) (available at http://csdd.tufts.edu/NewsEvents/NewsArticle. asp?newsid=69).

Circuit held that Michigan's fraud-on-the-FDA exception to drug manufacturer immunity is preempted by federal law; disagreeing, the Second Circuit held that state-law tort claims invoking that exception are *not* preempted. Nor can the Second Circuit's rationale be squared with the approach that other federal appeals courts have adopted in cases raising preemption issues. Review is warranted to resolve this conflict on an important and recurring issue of federal law.

Indeed, the Second Circuit could not have been clearer in expressing its disagreements both with *Garcia*'s holding and its major premises. For example, the Second Circuit stated explicitly, "We disagree," in response to the Sixth Circuit's assertion that there is "no meaningful difference" between *Buckman* and the preemption issue raised herein. Pet. App. 18a.

Garcia arose in a somewhat different factual context, but that difference does not diminish the irreconcilable nature of the conflict between the Second and Sixth Circuits on the questions presented herein. In *Garcia*, the plaintiff sought invalidation of MCL § 600.2946(5) in its entirety. The Sixth Circuit agreed with the plaintiff that *Buckman* required a finding that Michigan's fraud-on-the-FDA exception was preempted – at least where (as was true in that case) FDA had not itself concluded that it had been defrauded. *Garcia*, 385 F.3d at 966. But the Sixth Circuit rejected the plaintiff's argument that the preemption finding required invalidation of the entire statute. Rather, citing Michigan's general severability clause,[4] the Sixth Circuit held that the remainder of MCL § 600.2946(5) (*i.e.*,

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[4] MCL § 8.5 ("If any portion of an act or the application thereof to any person or circumstance shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application . . ., and to this end acts are declared to be severable.").

those portions remaining following excision of the exceptions set forth in (a) and (b)) should continue in force. *Id.* at 967. The court said, "Given a choice between immunity absent a finding of bribery or fraud by the Federal Government and no immunity, the Michigan Legislature would prefer the former option." *Id.*

In other words, although the Sixth Circuit was not faced with a claim that the defendant manufacturer had defrauded the FDA,[5] the legal issue it decided was the precise issue decided by the Second Circuit in this case, and the two appeals courts decided the issue in an irreconcilably conflicting manner.

Moreover, this case provides a particularly good vehicle for addressing the conflict, because the preemption issue is the *only* issue on which the two appeals courts disagreed. In particular, hearing this case would not require the Court to focus on issues peculiar to Michigan law, because the Second Circuit did not disagree with the Sixth Circuit's severability analysis. To the contrary, the Second Circuit made clear that it deemed itself bound to follow the Sixth Circuit's interpretation of Michigan law, in light of Michigan's location within the Sixth Circuit. Pet. App. 10a (citing *Factors Etc., Inc. v. Pro Arts, Inc.*, 625 F.2d 278, 279 (2d Cir. 1981)).[6] Accordingly, had the

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[5] In granting summary judgment, the district court had held that the plaintiff failed to submit evidence supporting her fraud-on-the-FDA claim, and the plaintiff did not appeal from that holding. *Id.* at 964 n.1.

[6] A Michigan state appellate court recently adopted *Garcia*'s preemption analysis as well as its severability analysis regarding the remainder of MCL § 600.2946(5). *Duronio v. Merck & Co.*, 2006 Mich. App. LEXIS 1841, *17 (Mich. App. June 13, 2006) ("Although we are not bound to follow the decision in *Garcia*, . . . we agree with its holding that [MCL § 600.2946(5)'s] fraud-on-the-FDA exception is

(continued...)

Second Circuit adopted Garcia's preemption analysis, one can confidently predict that the court would have upheld the district court's dismissal of all claims against Warner-Lambert.

As the Petition explains in detail, the Second Circuit's preemption analysis also conflicts with the analysis adopted by the Third and Ninth Circuits. Pet. 8-9. The Second Circuit held that *Buckman* does not require preemption of a state-law cause of action unless a claim of fraud-on-the-FDA is the *sole* basis of the cause of action. Pet. App. 19a-23a. In contrast, the Third and Ninth Circuits have adopted an analytic approach akin to the Sixth Circuit's in *Garcia*: a state-law cause of action is preempted any time the plaintiff, in order to prevail, is required to demonstrate that a federal agency has been defrauded, and the resultant inquiry would require the state courts and juries to second-guess the agency's decision-making. *See Nathan Kimmel, Inc. v. DowElanco,* 275 F.3d 1199, 1205-06 (9th Cir. 2001); *Michael v. Shiley*, 46 F.3d 1316, 1329 (3d Cir. 1995).

An inevitable consequence of allowing the conflict between the Second and Sixth Circuits to persist would be a significant increase in forum shopping among Michigan residents seeking to assert product liability claims against manufacturers of FDA-approved products. Any such manufacturer that does business within the states comprising the Second Circuit (and virtually every large pharmaceutical or medical device company does so) will likely discover that *all* product liability claims filed against them by Michigan residents are filed in Connecticut, New York, or Vermont. In many cases, the plaintiffs' choice of a forum outside their native Michigan will be outcome determinative regarding whether their claims

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[6](...continued)
preempted by federal law unless the FDA itself determines that it was defrauded.").

are barred by Michigan's tort reform statute. The significant potential for such forum shopping provides an additional reason for granting review.

The importance of the conflict between the circuits is heightened in light of the frequent resort to Multidistrict Litigation (MDL) proceedings in federal-court product liability actions involving FDA-approved products. Respondents' claims, for example, were transferred by the Judicial Panel on Multidistrict Litigation from federal court in Michigan to the Rezulin MDL in the U.S. District Court for the Southern District of New York. Federal law requires that such a claim be remanded "at or before the conclusion of . . . pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated." 28 U.S.C. § 1407(a).[7] Thus, it is virtually certain that these claims will eventually return to Michigan federal district courts, which are, of course, bound by Sixth Circuit decisions. Any such return would almost surely reignite the dispute between the parties regarding preemption – federal law is unsettled regarding whether transferor courts must, after a remand, follow the law of the case established by the consolidation court or, conversely, follow the clearly established law of the circuit within which they sit.

Indeed, then-Judge Ruth Bader Ginsberg faced precisely this dilemma in an appeal from MDL proceedings conducted by the U.S. District Court for the District of Columbia. She authored a decision for the D.C. Circuit that decided airline damage-limitations issues in a manner that conflicted with a prior Second Circuit decision. *In re Korean Air Lines Disaster*, 829 F.2d 1171, 1173-76 (D.C. Cir. 1987), *aff'd* 490 U.S. 122

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[7] This Court has held that remand of a non-terminated case following completion of pretrial proceedings is *mandatory*. *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

(1989). But the D.C. Circuit recognized that some of the consolidated cases would eventually be returned to courts within the Second Circuit, and conceded that "our circuit is not positioned to speak the last word" on whether those transferor courts would apply the D.C. Circuit rule or the conflicting Second Circuit rule. *Id.* at 1176. That conundrum was avoided only because this Court ultimately granted review and adopted the D.C. Circuit's position. *Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122 (1989). Unless the Court similarly grants the Petition in this case and resolves the conflict between the Second and Sixth Circuits, it may eventually be faced with the spectacle of two federal appeals court issuing conflicting decisions *in the very same case.*[8]

III. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH *BUCKMAN* AND THIS COURT'S OTHER PREEMPTION DECISIONS

Review is also warranted because the decision below is so clearly at odds with *Buckman* and other decisions of this Court that have addressed federal preemption claims.

Buckman involved state-law claims that a medical device manufacturer made fraudulent misrepresentations to FDA for the purpose of obtaining FDA approval for its device. The plaintiffs contended that FDA would not have approved the

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[8] At least one federal appeals court – the Eleventh Circuit – has stated its unwillingness to apply law of the case doctrine in a case transferred to a district court within the circuit, when doing so would require it to ignore its own binding precedent. *Murphy v. F.D.I.C.*, 208 F.3d 959, 967 (11th Cir. 2000) (refusing to abide by a pre-transfer D.C. Circuit decision, the court explained, "we are not, therefore, bound by the 'law of the case' doctrine to adhere to a ruling with which we have emphatically and repeatedly disagreed").

device (and thus they never would have been injured by the product) but for the fraud. The Court unanimously held that Congress had impliedly intended to preempt such state-law fraud-on-the-FDA claims when it adopted the FDCA, because adjudication of such claims would conflict with the FDA product-approval process. *Buckman*, 531 U.S. at 348. The Court identified numerous ways in which judicial re-examination of fraud-on-the-FDA issues would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, including that it would: (1) conflict with FDA's responsibility to address fraud allegations in a flexible manner, so as not to interfere (for example) with the right of physicians to prescribe FDA-approved products for uses not approved by FDA; (2) discourage manufacturers from seeking approval of medical products with potentially beneficial off-label uses; and (3) cause applicants seeking product approval to submit a deluge of information to FDA that it neither wants nor needs, thereby delaying approval of new products. *Id.* at 349-51.[9]

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[9] In its *amicus* brief urging the Court to hold that fraud-on-the-FDA causes of action are preempted, the United States highlighted yet another practical concern: permitting such suits to go forward will lead to numerous demands to depose FDA officials. The United States asserted:

> [W]idespread litigation could be expected on whether testimony and other evidence could be secured from FDA. . . . The prospect of such intrusive inquiries and attendant litigation would pose a significant potential for diverting FDA's resources from the important health mission that Congress has assigned to it and for distorting FDA's internal decisionmaking process.

Buckman Co. v. Plaintiffs' Legal Comm., No. 98-1768 (Brief for the United States as *Amicus Curiae* Supporting Petitioner) at 29 (Sept.

(continued...)

The Second Circuit did not dispute that permitting courts to examine whether FDA has been defrauded raises the concerns identified in *Buckman*, regardless whether that examination occurs in connection with a state-law fraud-on-the-FDA cause of action or in connection with determining the applicability of Michigan's fraud-on-the-FDA exception to the bar on drug manufacturer liability. *Buckman* held that the concerns it identified demonstrated that Congress had impliedly preempted fraud-on-the-FDA causes of action, because such judicial inquiries stood as an obstacle to the accomplishment of Congress's objectives.[10] The Second Circuit nonetheless held that the presumption against preemption of state-law tort actions raising traditional common law claims served to distinguish this case from *Buckman*. Pet. App. 18a-24a.

The Second Circuit badly misconstrued the presumption against preemption. Any such presumption is merely a tool to assist in deciding the ultimate issue in a preemption case: did Congress intend to prevent State and local governments from exercising authority over an issue of concern to the federal government?[11] As the Court has repeatedly emphasized, "Preemption fundamentally is a question of congressional intent." *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990).

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[9](...continued)
2000).

[10] Implied conflict preemption is said to occur "when a state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605 (1991) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

[11] It is beyond dispute that when Congress chooses to preempt State and local regulation of commerce, it is entitled to do so under the Supremacy Clause. U.S. Const., art. VI, cl. 2.

Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) ("'[t]he purpose of Congress is the ultimate touchstone' of preemption analysis") (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486-87 (1996) ("any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *congressional purpose.*'") (emphasis in original) (quoting *Cipollone*, 505 U.S. at 530 n.27 (opinion of Stevens, J.)).

When Congress's purpose is obscure, the presumption against preemption is a rule of construction that helps reveal that purpose. But thanks to *Buckman*, we *already know* what Congress intended: Congress sought to prevent States from second-guessing FDA product-approval decisions in a manner that causes the types of administrative difficulties described in *Buckman*, because Congress believed that such activities would stand as an obstacle to the accomplishment of FDA's objectives. Because the administrative difficulties identified in *Buckman* also arise when a court undertakes to determine whether MCL § 600.2946(5)'s fraud-on-the-FDA exception applies, we already know from *Buckman* that Congress intended to preempt such judicial inquiries. Under those circumstances, there is no need to resort to tie-breaking presumptions to discern congressional intent. The Second Circuit erred in applying the presumption against preemption as its basis for discerning a congressional purpose wholly at odds with the purpose discerned in *Buckman*.

The Second Circuit apparently based its ruling on a concern that a preemption finding would be tantamount to holding that Congress had intended to "gut[] traditional state law duties between pharmaceutical companies and their consumers." Pet. App. 20a. That concern was not well-founded. It is the Michigan legislature, not Congress, that determined – when it adopted MCL § 600.2946(5) – that a

major restructuring of traditional state law duties was appropriate, in order to ensure that excessive product liability litigation did not undermine effective health care. Regardless how the Court rules on this preemption issue, the Michigan legislature will be free to restore traditional common law duties any time it deems appropriate.

In finding against preemption, the Second Circuit relied on this Court's decision in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), which rejected a claim that federal regulation of nuclear power preempted a common law suit against a nuclear power plant operator. That reliance was misplaced. As *Buckman* explained, the *Silkwood* decision "turned on specific statutory evidence that Congress 'disclaimed any interest in promoting the development and utilization of atomic energy by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials.'" *Buckman*, 531 U.S. at 352 (quoting *Silkwood*, 464 U.S. at 257). There is no similar statutory evidence here; to the contrary, as the Petition explains in detail, all the statutory evidence indicates that (as *Buckman* held) Congress intended to preempt all common law causes of action that require second-guessing of FDA product-approval determinations.

Finally, the Second Circuit – in conflict with numerous decisions of this Court – essentially wrote off much of the doctrine of implied preemption. The court held that when a state-law tort action is designed to enforce the historic police powers of the State, Congress should *never* be deemed to have intended to preempt the action based solely on concerns that the court would be required to examine fraud-on-the-FDA issues, unless Congress has expressed that intent "explicitly." Pet. App. 24a. This Court repeatedly has made clear that Congress can be deemed to have intended to preempt state law even when it has not said so explicitly. If Congress's express language

does not directly answer the preemption question at issue, "courts must consider whether the federal statute's 'structure and purpose,' or nonspecific statutory language nonetheless reveal a clear, but implicit, preemptive intent." *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 20 (1996) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Review is warranted because the Second Circuit's decision is so badly out of step with this Court's preemption case law.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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Dated: July 20, 2007

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No. 06-1498

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC AND PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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NOTICE

The following documents have been omitted in the printing of this Joint Appendix. They may be found in the Petitioner's Appendix to the 06-1498 Petition For A Writ Of Certiorari at the following pages.

Desiano v. *Warner-Lambert Co.*, No. 05-1705-cv (2d Cir. Feb. 12, 2007) (order denying rehearing and rehearing en banc) 39a

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Class Action Complaint and Demand for Jury-Trial, *Kent et al. v. Warner-Lambert Co. et al.*, No. 01-71806 (E.D. Mich. filed Apr. 17, 2001) 341a

Complaint and Demand for Jury Trial, *Sherman et al. v. Warner-Lambert Co. et al.*, No. 03-70501 (E.D. Mich. filed Jan. 5, 2003) 351a

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
(Foley Square)

CIVIL DOCKET FOR CASE #: 1:00-cv-05117-LAK

KENT, *et al.*,
Plaintiffs,

v.

WARNER-LAMBERT CO., *et al.*,
Defendants.

RELEVANT DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
07/12/2000	1	Filed True Copy of Order from MDL Panel transferring action from U.S.D.C. for the Eastern District of Michigan, Docket # 2:00-cv-71806 ; Mailed letter requsting transfer of their file. (bm) Modified on 07/14/2000 (Entered 07-14-2000)
		* * * *
07/12/2000		Case accepted as related to MDL # 1348 & M21-85. (bm) (Entered: 07/14/2000)
07/25/2000		Certified copy of transfer order and file received from Eastern District of Michigan MDL# 1348. (bm) (Entered: 07/25/2000)
		* * * *

DATE	NO.	PROCEEDINGS
10/17/2000		Consolidated Member Case. Lead Case Number: 1:00cv2843 . (dcap) (Entered: 10/19/2000)
		* * * *
01/26/2001	4	ANSWER to Amended Complaint by Warner-Lambert Co., Parke-Davis Division (Attorney David Klingsberg from the Firm: Kaye, Scholer). (jp) (Entered: 01/30/2001)
		* * * *
01/25/2005		MOTION for an Order pursuant to Rule 12(c) of the FRCP entering Judgment on the Pleadings on all claims asserted by plaintiffs. Declaration of Wendy S. Dowse in support attached. Document filed by Warner-Lambert Company, Parke-Davis Division. Original entry in 00cv2843 document number 2798. (yv,) (Entered: 01/28/2005)
01/25/2005		MEMORANDUM OF LAW in Support re: [2798] MOTION for Judgment on the Pleadings. Document filed by Pfizer, Inc., Warner Lambert Company, Parke-Davis. Original entry in 00cv2843 document number 2799. Filed In Associated Cases: 1:00-cv-02843-LAK-GWG,1:00-cv-05117-LAK, 1:01-cv-02242-LAK, 1:03-cv-03488-LAK (yv,) Modified on 1/28/2005 (yv,). (Entered: 01/28/2005)
		* * * *

DATE	NO.	PROCEEDINGS
02/18/2005	8	REPLY MEMORANDUM OF LAW in Support re: [2798] MOTION for Judgment on the Pleadings. Document filed by Pfizer, Inc., Warner Lambert Company, Parke-Davis. Original entry in 00cv2843 document number 2922. Filed In Associated Cases: 1:00-cv-02843-LAK-GWG, 1:00-cv-05117-LAK, 1:03-cv-03488-LAK, 01-cv-9817-LAK (yv,) Modified on 3/2/2005 (yv,). (Entered: 03/02/2005)
02/28/2005	7	PRETRIAL ORDER NO. 355 (Michigan Plaintiffs – Motion for Judgment on the Pleadings) Defendants' motion for judgment on the pleadings dismissing the complaints is granted for the reasons stated on the record in open court this day (Signed by Judge Lewis A. Kaplan on 2/24/05) Original entry in 00cv2843 document number 2918. Filed In Associated Cases: 1:01-cv-0050-LAK,1:01-cv-9817-LAK, 1:04-cv-3957-LAK, 1:00-cv-02843-LAK-GWG, 1:00-cv-05117-LAK, 1:01-cv-02242-LAK,1:03-cv-03488-LAK, 1:04-cv-10031-LAK(yv,) Modified on 3/1/2005 (yv,). (Entered: 03/01/2005)
03/02/2005		CLERK'S JUDGMENT That for the reasons stated in the Court's Order dated February 24, 2005, defendants? [sic] motion for judgment on the pleadings dismissing the complaints

DATE	NO.	PROCEEDINGS
		are granted. (Orig. filed in case no. 00 Civ. 2843 (LAK) as doc. # 2926). (Signed by J. Michael McMahon, clerk on 3/2/05) (ml,) (Entered: 03/02/2005)
03/07/2005		Mailed notice of Right to Appeal re: Clerk's Judgment, and to Attorney(s) of Record: Wendy Sabina Dowse, Steven Glickstein, David Klingsberg, Bonnie L. Mayfield, John D. Peters, Daniel J. Stephenson. (lma,) (Entered: 03/08/2005)
03/25/2005		NOTICE OF APPEAL from [7] Pretrial Order. Document filed by Kimberly Kent, Emmett Kent. Filing fee $ 255.00, receipt number E 538534. Copies of Notice of Appeal mailed to Attorney(s) of Record: Kaye Scholer, L.L.P.; Lieff, Cabraser, Heimann & Bernstein, L.L.P.; Mathis & Adams, P.C.; Charfoos & Christensen, P.C.;. Goldberg, Persky & White, P.C.; Christopher S. Varjabedian, P.C. ORIGINAL DOCUMENT ENTERED IN CASE# 00cv2843, DOC. #2990) (tp,) (Entered: 03/30/2005)
03/30/2005		Transmission of Notice of Appeal and Certified Copy of Docket Sheet to US Court of Appeals re: Notice of Appeal. (tp,) (Entered: 03/30/2005)
03/30/2005		Transmission of Notice of Appeal to the District Judge re: Notice of Appeal. (tp,) (Entered: 03/30/2005)

DATE	NO.	PROCEEDINGS
04/19/2005	9	ENDORSED LETTER addressed to Judge Kaplan from David Klingsberg dated 4/7/05 re: clarification of Sections 2.a & b of Pretrial Order 366 insofar as it refers to a 12/1/03 discovery deadline. The origin or the 12/1/03 date is arbitrary (Signed by Judge Lewis A. Kaplan on 4/14/05) (yv,) (Entered: 04/20/2005)

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
(Foley Square)

CIVIL DOCKET FOR CASE #: 1:01-cv-09817-LAK

ARMSTRONG, *et al.*,
Plaintiffs,

v.

WARNER-LAMBERT CO., *et al.*,
Defendants.

RELEVANT DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
11/07/2001	1	CERTIFIED TRUE COPY OF CONDITIONAL MDL TRANSFER IN ORDER FROM THE MDL PANEL...transferring action from the U.S.D.C. for the Eastern District of Michigan, Docket No.: 2:01-cv73249, MDL No.: 1348, M No.: 21-85, to the S.D.N.Y. Mailed letter requesting transfer of their file. (db) (Entered: 11/08/2001)
		* * * *
11/07/2001		Case accepted as related to MDL 1348 & M 21-85. (db) (Entered: 11/08/2001)
11/08/2001		MDL Transfer In: Received Certified Copy of docket entries and file from the District of Michigan, Docket No.: 2:01cv73249, MDL No.: 1348. (gmo) (Entered: 01/10/2002)

DATE	NO.	PROCEEDINGS

* * * *

12/17/2004		RULE 7.1 DISCLOSURE STATEMENT. Document filed by Parke-Davis Division, Warner-Lambert Company. Received in night deposit box on 12/17/04 at 5:48 p.m. Original entry in 00cv2843 document number 2746.(yv,) (Entered: 12/21/2004)
12/17/2004		MOTION for an Order pursuant to FRCP 6(b)(2) allowing defendant to serve and file an answer out of time. Affirmation of Steven Glickstein in support attached. Document filed by Parke-Davis Division, Warner-Lambert Company. Received in night deposit box on 12/17/04 at 5:48 p.m. Original entry in 00cv2843 document number 2747. (yv,) (Entered: 12/21/2004)
12/17/2004		MEMORANDUM OF LAW in Support re: MOTION for an Order pursuant to FRCP 6(b)(2) allowing defendant to serve and file an answer out of time. Document filed by Parke-Davis Division, Warner-Lambert Company. Received in night deposit box on 12/17/04 at 5:48 p.m. Original entry in 00cv2843 document number 2748. (yv,) (Entered: 12/21/2004)

DATE	NO.	PROCEEDINGS
01/14/2005		PRETRIAL ORDER NO. 341 (Armstrong - Motion for Extension of Time) Defendant's motion for leave to serve and file an answer out of time, which is not opposed, is granted (Signed by Judge Lewis A. Kaplan on 1/13/05) Copies mailed by Chambers. Original entry in 00cv2843 document number 2784.(yv,) (Entered: 01/17/2005)
01/18/2005		ANSWER to Complaint with JURY DEMAND. Document filed by Parke-Davis Division, Warner-Lambert Company. Original entry in 00cv2843 document number 2792. (yv,) (Entered: 01/19/2005)
01/25/2005		MOTION for an Order pursuant to Rule 12(c) of the FRCP entering Judgment on the Pleadings on all claims asserted by plaintiffs. Declaration of Wendy S. Dowse in support attached. Document filed by Parke-Davis Division, Warner-Lambert Company. Original entry in 00cv2843 document number 2798. (yv,) (Entered: 01/28/2005)
01/25/2005		MEMORANDUM OF LAW in Support re: MOTION for Judgment on the Pleadings. Document filed by Parke-Davis Division, Warner-Lambert Company. Original entry in 00cv2843 document number 2799. (yv,) (Entered: 01/28/2005)

DATE	NO.	PROCEEDINGS
02/14/2005	2	REPLY MEMORANDUM OF LAW in Support re: MOTION for Judgment on the Pleadings. Document filed by Parke-Davis Division, Warner-Lambert Company. Original entry in 00cv2843 document number 2922. (yv,) (Entered: 03/02/2005)
		* * * *
02/28/2005		PRETRIAL ORDER NO. 355 (Michigan Plaintiffs - Motion for Judgment on the Pleadings) Defendants' motion for judgment on the pleadings dismissing the complaints is granted for the reasons stated on the record in open court this day (Signed by Judge Lewis A. Kaplan on 2/24/05) Original entry in 00cv2843. document number 2918.(yv,) (Entered: 03/01/2005)
03/02/2005		CLERK'S JUDGMENT. That for the reasons stated in the Court's Order dated February 24, 2005, defendants? [sic] motion for judgment on the pleadings dismissing the complaints are granted. (Orig. filed in case no. 00 Civ. 2843 (LAK) as doc. # 2926). (Signed by J. Michael McMahon, clerk on 3/2/05) (ml,) (Entered: 03/02/2005)
03/07/2005		Mailed notice of Right to Appeal and to Attorney(s) of Record: Wendy Sabina Dowse, Steven Glickstein, David Klingsberg, John D. Peters, Alan Edward Rothman. (lma,) (Entered: 03/08/2005)

DATE	NO.	PROCEEDINGS
03/25/2005		NOTICE OF APPEAL from Pretrial Order. Document filed by Michael W. Herndon, Michael Kanakry, Mary Ann Kanakry, Julia Martin, Royal M. Martin, Janice L. Kimmel, Mona Przytulski, David A. Rice, Anita Schultz, Richard P. Schultz, Connie Armstrong, James K. Soukup, Jennifer St. Pierre, Donald Waun, Jeanene Waun, Lauranane Bradley, Raymond Bradley, Sr, Glenn Chandler, Billie Flynt, Shelly Grotenhius, Judy Hearn, Colleen Herndon. Filing fee $ 255.00, receipt number E 538534. Copies of Notice of Appeal mailed to Attorney(s) of Record: Kaye Scholer, L.L.P.; Lieff, Cabraser, Heimann & Bernstein, L.L.P.; Mathis & Adams, P.C.; Charfoos & Christensen, P.C.; Goldberg, Persky & White, P.C.; Christopher S. Varjabedian, P.C. ORIGINAL DOCUMENT ENTERED IN CASE #00cv2843, DOC. #2990. (tp,) (Entered: 03/30/2005)
03/30/2005		Transmission of Notice of Appeal and Certified Copy of Docket Sheet to US Court of Appeals re: Notice of Appeal. (tp,) (Entered: 03/30/2005)
03/30/2005		Transmission of Notice of Appeal to the District Judge re: Notice of Appeal. (tp,) (Entered: 03/30/2005)

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
(Foley Square)

CIVIL DOCKET FOR CASE #: 1:03-cv-03488-LAK

SHERMAN, *et al.*,
Plaintiffs,

v.

WARNER-LAMBERT CO., *et al.*,
Defendants.

RELEVANT DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
05/15/2003	1	CERTIFIED TRUE COPY OF CONDITIONAL MDL TRANSFER IN ORDER FROM THE MDL PANEL...transferring action from the U.S.D.C. for the Eastern District of Michigan, Docket No.: 2:03cv70501, MDL No.: 1348,, to the S.D.N.Y. Mailed letter requesting transfer of their file. (laq) (Entered: 05/20/2003)
		* * * *
05/15/2003		Case accepted as related to 1:00cv2843 and M21-85. Notice of assignment to follow. (laq) (Entered: 05/20/2003)
05/15/2003		CONSOLIDATED MDL CASE: Case consolidated with 1:00-cv-2843 (yv,) (Entered: 06/17/2004)

DATE	NO.	PROCEEDINGS
06/03/2003		MDL TRANSFER IN: Received certified copy of docket entries and file from the District of Eastern District of Michigan, Docket No.: 03cv70501, MDL No.: 1348. (gf) (Entered: 06/09/2003)
		* * * *
01/25/2005		MOTION for an Order pursuant to Rule 12(c) of the FRCP entering Judgment on the Pleadings on all claims asserted by plaintiffs. Declaration of Wendy S. Dowse in support, attached. Document filed by Warner-Lambert Co., Parke-Davis. Original entry in 00cv2843 document number 2798. (yv,) (Entered: 01/28/2005)
01/25/2005		MEMORANDUM OF LAW in Support re: [2798] MOTION for Judgment on the Pleadings. Document filed by Pfizer, Inc., Warner Lambert Company, Parke-Davis. Original entry in 00cv2843 document number 2799. Filed In Associated Cases: 1:00-cv-02843-LAK, 1:00-cv-05117-LAK,1:01-cv-02242-LAK, 1:03-cv-03488-LAK (yv,) Modified on 1/28/2005 (yv,). (Entered: 01/28/2005)

DATE	NO.	PROCEEDINGS

* * * *

02/18/2005	4	REPLY MEMORANDUM OF LAW in Support re: [2798] MOTION for Judgment on the Pleadings. Document filed by Pfizer, Inc., Warner Lambert Company, Parke-Davis. Original entry in 00cv2843 document number 2922. Filed In Associated Cases: 1:00-cv-02843-LAK-GWG, 1:00-cv-05117-LAK,1:03-cv-03488-LAK, 01-cv-9817-LAK(yv,) Modified on 3/2/2005 (yv,). (Entered: 03/02/2005)
02/28/2005	3	PRETRIAL ORDER NO. 355 (Michigan Plaintiffs - Motion for Judgment on the Pleadings) Defendants' motion for judgment on the pleadings dismissing the complaints is granted for the reasons stated on the record in open court this day (Signed by Judge Lewis A. Kaplan on 2/24/05) Original entry in 00cv2843 document number 2918. Filed In Associated Cases: 1:01-cv-0050-LAK,1:01-cv-9817-LAK, 1:04-cv-3957-LAK, 1:00-cv-02843-LAK-GWG, 1:00-cv-05117-LAK, 1:01-cv-02242-LAK,1:03-cv-03488-LAK, 1:04-cv-10031-LAK (yv,) Modified on 3/1/2005 (yv,). (Entered: 03/01/2005)

DATE	NO.	PROCEEDINGS
03/02/2005		CLERK'S JUDGMENT That for the reasons stated in the Court's Order dated February 24, 2005, defendants? [sic] motion for judgment on the pleadings dismissing the complaints are granted. (Orig. filed in case no. 00 Civ. 2843 (LAK) as doc. # 2926). (Signed by J. Michael McMahon, clerk on 03/02/05) (ml,) (Entered: 03/02/2005)
03/07/2005		Mailed notice of Right to Appeal re: Clerk's Judgment, and to Attorney(s) of Record: Wendy Sabina Dowse, Steven Glickstein, David Klingsberg, Bonnie L. Mayfield, John D. Peters, Maris Veidemanis. (Ima,) (Entered: 03/08/2005)
03/25/2005		NOTICE OF APPEAL from [3] Pretrial Order. Document filed by Linda Sherman. Filing fee $255.00, receipt number E 538534. Copies of Notice of Appeal mailed to Attorney(s) of Record: Kaye Scholer, L.L.P.; Lieff, Cabraser, Heimann & Bernstein, L.L.P.; Mathis & Adams, P.C.; Charfoos & Christensen, P.C.; Goldberg, Persky & White, P.C.; Christopher S. Varjabedian, P.C. ORIGINAL DOCUMENT ENTERED IN CASE #00cv2843, DOC. #2990. (tp,) (Entered: 03/30/2005)

DATE	NO.	PROCEEDINGS
03/30/2005		Transmission of Notice of Appeal and Certified Copy of Docket Sheet to US Court of Appeals re: Notice of Appeal. (tp,) (Entered: 03/30/2005)
03/30/2005		Transmission of Notice of Appeal to the District Judge re: Notice of Appeal. (tp,) (Entered: 03/30/2005)

* * * *

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
(Foley Square)

CIVIL DOCKET FOR CASE #: 1:04-cv-03957-LAK

FISHER, *et al.*,
Plaintiffs,

v.

PFIZER, INC., *et al.*,
Defendants.

RELEVANT DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
05/25/2004	1	CERTIFIED TRUE COPY OF CONDITIONAL MDL TRANSFER IN ORDER FROM THE MDL PANEL... transferring this action from the United States District Court - Eastern District of Kentucky, Case Number: 2:04-cv-70880, MDL Number: MDL 1348. (Signed by Judge MDL Panel on 4/23/04) (laq,) (Entered: 06/02/2004)
		* * * *
06/28/2004		MDL TRANSFER IN: Received certified copy of docket entries and documents numbered 1-6 from the United States District Court - Eastern District of Michigan. Case Number: 2:04-cv-70880 (PJD), MDL Number: MDL 1348. (jjm,) (Entered: 07/27/2004)

DATE	NO.	PROCEEDINGS

* * * *

01/25/2005		MOTION for an Order pursuant to Rule 12(c) of the FRCP entering Judgment on the Pleadings on all claims asserted by plaintiffs. Declaration of Wendy S. Dowse in support attached. Document filed by Warner-Lambert Company, Parke-Davis, Pfizer, Inc. Original entry in 00cv2843 document number 2798. (yv,) (Entered: 01/28/2005)
01/25/2005		MEMORANDUM OF LAW in Support re: MOTION for Judgment on the Pleadings. Document filed by Warner-Lambert Company, Parke-Davis, Pfizer, Inc. Original entry in 00cv2843 document number 2799. (yv,) (Entered: 01/28/2005)
02/08/2005	3	RESPONSE to Motion re: MOTION for Judgment on the Pleadings.. Document filed by Nancy Fisher. (cd,) (Entered: 02/15/2005)

DATE	NO.	PROCEEDINGS
02/16/2005		REPLY MEMORANDUM OF LAW in Support re: MOTION for Judgment on the Pleadings. Document filed by Warner-Lambert Company, Parke-Davis, Pfizer, Inc. Original entry in 00cv2843 document number 2891. (yv,) (Entered:. 02/18/2005)
		* * * *
02/24/2005	4	RESPONSE to Motion re: MOTION for Judgment on the Pleadings. Document filed by Nancy Fisher. (cd,) (Entered: 03/04/2005)
02/28/2005		PRETRIAL ORDER NO. 355 (Michigan Plaintiffs - Motion for Judgment on the Pleadings) Defendants' motion for judgment on the pleadings dismissing the complaints is granted for the reasons stated on the record in open court this day (Signed by Judge Lewis A. Kaplan on 2/24/05) Original entry in 00cv2843 document number 2918.(yv,) (Entered: 03/01/2005)
03/02/2005		CLERK'S JUDGMENT That for the reasons stated in the Court's Order dated February 24, 2005, defendants? [sic] motion for judgment on the pleadings dismissing the complaints are granted. (Orig. filed in case no. 00 Civ. 2843 (LAK) as doc. # 2926). (Signed by J. Michael McMahon, clerk on 3/2/05) (ml,) (Entered: 03/02/2005)

DATE	NO.	PROCEEDINGS
03/07/2005		Mailed notice of Right to Appeal re: Clerk's Judgment, and to Attorney(s) of Record: Wendy Sabina Dowse, Vanessa G. Fluker, Steven Glickstein, David Klingsberg, Bonnie L. Mayfield, Daniel J. Stephenson. (lma,) (Entered: 03/08/2005)
03/25/2005		NOTICE OF APPEAL from Pretrial Order. Document filed by Nancy Fisher. Filing fee $255.00, receipt number E 538534. Copies of Notice of Appeal mailed to Attorney(s) of Record: Kaye Scholer, L.L.P.; Lieff, Cabraser, Heimann & Bernstein, L.L.P.; Mathis & Adams, P.C.; Charfoos & Christensen, P.C.; Goldberg, Persky & White, P.C.; Christopher S. Varjabedian, P.C. ORIGINAL DOCUMENT ENTERED IN CASE #00cv2843, DOC. #2990. (tp,) (Entered: 03/30/2005)
03/30/2005		Transmission of Notice of Appeal and Certified Copy of Docket Sheet to US Court of Appeals re: Notice of Appeal. (tp,) (Entered: 03/30/2005)
03/30/2005		Transmission of Notice of Appeal to the District Judge re: Notice of Appeal. (tp,) (Entered: 03/30/2005)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCIT

Docket No.[s] : 05-1705-cv(L), 05-1743-cv,
05-1745-cv (CON)

CAESAR DESIANO AND GLORIA DESIANO, *et al.*,
Plaintiffs-Appellants,

v.

WARNER LAMBERT CO., *et al.*,
Defendants-Appellees.

RELEVANT DOCKET ENTRIES

DATE	PROCEEDINGS
4/1/05	Copy of notice of appeal and district court docket entries on behalf of Gloria Desiano *et. al.* filed. [Entry date Apr 21 2005] [YK]
	* * * *
5/20/05	Order filed stating a pre-argument conference was held on May 13, 2005 in In re Rezulin Products Liab. Litig., 2d Cir.Dkt. Nos. 05-1743cv; 05-1745cv. Because all of the above referenced appeals stem from Judge Kaplan's Order in In re Rezulin Products Liab. Litig., MDL No. 1348, IT IS HEREBY ORDERED that all the above referenced appeals be, and hereby are CONSOLIDATED for all purposes. In re Rezulin Products Liab Litig., 2d Cir Dkt. No. 05-1705-cv(L) shall be designated accordingly

DATE	PROCEEDINGS
	as the lead appeal. (FS) [Entry date May 25 2005] [AM]
5/25/05	Notice to counsel in re: Order filed 5/20/05. [Entry date May 25 2005] [AM]
	* * * *
6/29/05	APPELLANT Davis, Alicia Miller, Barbara Fleming, Connie Gibson, ET AL , brief FILED with proof of service. [Entry date Jun 30 2005] [NG]
6/29/05	APPELLANT Davis, Alicia Miller, Barbara Fleming, Connie Gibson, ET AL joint appendix filed w/pfs. [Entry date Jun 30 2005] [NG]
7/27/05	APPELLEE Warner Lambert Co., brief filed with proof of service. [Entry date Jul 27 2005] [CI]
8/18/05	APPELLANT Davis, Alicia Miller, Barbara Fleming, Connie Gibson, ET AL , reply brief filed with proof of service. [Entry date Aug 26 2005] [CI]
	* * * *
11/8/05	Case heard before FEINBERG, CALABRESI, PARKER, C.JJ CD DATE: 11/08/05 [Entry date Nov 8 2005] [RD]

DATE	PROCEEDINGS
6/28/06	Acevedo-Barreto, Aiello, Alfred, Aranda-Ramos, ET AL; APPELLANT Janet Smith, Mary Jones, Milbergo Reyes, ET AL; APPELLEE Parke-Davis, Patricia Black, 28(J) letter received from Steven Glick-stein, counsel for Defendants Appellees, dated 6/28/06. [Entry date Jun 28 2006] [JP]
10/5/06	Judgment of the district court is VACATED and REMANDED by published signed opinion filed. (GC) [Entry date Oct 5 2006] [AM]
10/5/06	Judgment filed. [Entry date Oct 5 2006] [AM]
10/5/06	Notice to counsel in re: Opinion filed 10/5/06. [Entry date Oct 5 2006] [AM]
	* * * *
10/17/06	Notice to counsel in re: Order FILED GRANTING to and inlcuding November 2, 2006, motion for a 14-day extension of time to file Petition for Rehearing and Rehearing en Banc by Appellee Warner Lambert Co., dated 10/17/06. [Entry date Oct 17 2006] [JP]
10/17/06	Appellee Warner Lambert Co. motion for a 14-day extension of time file Petition for Rehearing and Rehearing en Banc, filed with proof of service. [Entry date Oct 17 2006] [JP]

DATE	PROCEEDINGS
10/17/06	Order FILED GRANTING to and including November 2, 2006, motion for a 14-day extension of time to file Petition for Rehearing and Rehearing en Banc by Appellee Warner Lambert Co., endorsed on motion AH dated 10/17/2006. Extended Mandate due is 11/10/2006. Extended Petition for rehearing is 11/2/2006. [Entry date Oct 17 2006] [JP]
11/2/06	Warner-Lambert Company and Pfizer Inc., Petition for rehearing and petition for rehearing en bane filed with proof of service. [Entry date Nov 7 2006] [JP]
11/9/06	Movant Pharmaceutical Research and Manufactures of America motion file brief as amicus curiae in support of Defendants-Appellees' petition for Rehearing en Banc, filed with proof of service. [Entry date Nov 14 2006] [JP]
11/17/06	AMICUS CURIAE Pharmaceutical Research and Manufactures of America, brief in support of Petition for Rehearing filed with proof of service. [Entry date Jan 11 2007] [JP]
11/17/06	Order FILED GRANTING motion to file brief as amicus curiae in support of petition for rehearing by Amicus Curiae Pharmaceutical Research and Manufactures of America, endorsed on motion dated 11/9/2006. [Entry date Nov 21 2006] [JP]

DATE	PROCEEDINGS
11/21/06	Notice to counsel in re: Order FILED GRANTING motion to file brief as amicus curiae in support of petition for rehearing by Amicus Curiae. [Entry date Nov 21 2006] [JP]
1/18/07	Amended published signed opinion filed. (GC) [Entry date Jan 18 2007] [JP]
1/18/07	Amended Judgment filed. [Entry date Jan 18 2007] [JP]
	* * * *
1/31/07	Letter received from David Klinsberg Counsel for Appellees Warner-Lambert Company LLC and Pfizer Inc., dated 1/31/07 in re: advising this Court that the amended opinion does not alter the bases for rehearing and rehearing en banc set forth in the Petition. [Entry date Feb 6 2007] [JP]
2/12/07	Notice to counsel in re: Order FILED DENYING motion Petition for rehearing and petition for rehearing en banc by Appellees Defendants-Appellees Warner-Lambert Company LLC and Pfizer Inc. [Entry date Feb 12 2007] [JP]
2/12/07	Order FILED DENYING motion Petition for rehearing and petition for rehearing en banc by Appellees Defendants-Appellees Warner-Lambert Company LLC and Pfizer Inc. Entry date Feb 12 2007] [JP]

DATE	PROCEEDINGS
5/7/07	Judgment MANDATE ISSUED. CLOSED [Entry date May 7 2007] [JP]
5/7/07	Certified copy of the order filed 2/12/2007 issued to the district court, [informational only]. [Entry date May 7 2007] [JP]
5/8/07	Mandate receipt returned from the district court. [Entry date May 18 2007] [NS]
5/17/07	Notice of filing petition for Acevedo-Barreto, Aiello, Alfred, Aranda-Ramos, APPELLEES Kmart Corporation, Parke-Davis, Warner Lambert Co., ET AL , dated May 14, 2007 filed. Supreme Court #: 06-1498. [Entry date May 22 2007] [JP]
5/18/07	Mandate receipt returned from the district court. [Entry date May 18 2007] [DR]

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE
COUNTY OF WAYNE

No. 03-

NANCY FISHER, Individually; and NANCY FISHER,
Personal Representative of the
Estate of Troy Fisher, Deceased,
Plaintiffs,

v

PFIZER INC.; WARNER-LAMBERT COMPANY;
and PARKE-DAVIS, a division of
WARNER LAMBERT,
Defendants.

CHRISTOPHER S. VARJABEDIAN, P.C.
By: Vanessa G. Fluker P64870
Attorney for Plaintiffs
29777 Telegraph Road, Suite 2175
Southfield, Michigan 48034
(248) 355-0000

COMPLAINT AND JURY DEMAND

THERE IS NO OTHER PENDING OR RESOLVED CIVIL ACTION ARISING OUT OF THE TRANSACTION OR OCCURRENCE ALLEGED IN THIS COMPLAINT.

The plaintiffs say:

Jurisdiction / Venue Allegations

1. The parties reside in the following places:

   (a) Plaintiff Nancy Fisher resides in Wayne County, Michigan;

   (b) Defendant carries on a continuous and systematic part of its general business in Wayne County, Michigan.

2. This cause of action arose in Wayne County, Michigan.

3. The amount in controversy exceeds Twenty-Five Thousand and no/100 Dollars ($25,000.00), exclusive of interest, costs and attorney fees.

Factual Allegations

4. At issue in this case is defendants' concerted multi-year fraudulent and deceptive effort and pattern of practices to obtain, first, Food and Drug Administration ("FDA") approval for Rezulin, and, second, thereafter to reap the benefits of its commercial success. This is detailed hereinafter:

5. Type 2 diabetes is a life-threatening disease that affects 18 million Americans. It is a leading cause of coronary heart disease, blindness, kidney failure, and limb amputation.

6. On July 31, 1996, Warner-Lambert submitted a new drug application (NDA) for Rezulin with the

Food and Drug Administration. The company saw the drug as the next billion dollar blockbuster. And they were right. Sales to approximately 1.9 million diabetics generated revenues estimated at over $1.8 billion.

7. At the time the NDA was filed, Rezulin had already been selected as one of two drugs to be tested in a six-year, $150 million federally-funded Diabetes Prevention Program (DPP), a National Institutes of Health (NIH) clinical study examining ways to prevent or delay the onset of type 2 diabetes.

8. Rezulin's selection for the DPP was anything but a coincidence and illustrates a pattern of concealment, false and deceptive advertising and influence peddling to ensure the drug's success.

9. Dr. Richard C. Eastman, Director of the NIH's Division of Diabetes, Endocrinology and Metabolic Diseases, has been described as "the federal government's top diabetes researcher. [sic] In his own words, he had "overall global responsibility" for the DPP study. Dr. Eastman also wore another hat—Warner-Lambert employee. In his capacity as formal consultant to Warner-Lambert and as a member of the boards of two organizations financed by Warner-Lambert and the drug's developer, Sankyo Company—the "National Diabetes Education Initiative" and the "Rezulin National Speakers Bureau" —Dr. Eastman was an outspoken supporter of Rezulin. in exchange for that support, The Los Angeles Times reported that Dr. Eastman received in excess of $78,000 in compensation from Warner-Lambert and its affiliates.

10. With the NIH "seal of approval," FDA officials agreed to "fast-track" the drug and assigned John L.

Gueriguian, M.D. as the chief medical officer to oversee the six-month "priority" review.

11. After finding several serious health and safety concerns, Dr. Gueriguian recommended against approval of the drug in a detailed written evaluation dated October 9, 1996.

12. "I cited several reasons," Dr. Gueriguian explained in an interview published in the December 6, 1998 edition of The Los Angeles Times. "One of them was a telltale sign of very worrisome liver toxicity. I stand behind my review, absolutely."

13. Warner-Lambert's clinical trial data had shown that cases who had received Rezulin developed liver problems at four times the rate of controls who had received a placebo.

14. In addition to liver toxicity, Gueriguian had also expressed concerns about potential heart problems.

15. Gueriguian's review concluded, "Clearly, the sponsor has not made its case."

16. The negative recommendation came as no surprise to Warner-Lambert. Throughout his review of the drug, Dr. Gueriguian had "posed questions and expressed concerns to [Warner-Lambert's] director of worldwide regulatory affairs." In September 1996, Gueriguian had met with a Warner-Lambert representative and used "intemperate" language to describe the drug's prospects.

17. After the September 1996 meeting, the writing was not only on the wall, it was clearly on the way to being memorialized in a formal medical review and recommendation. Warner-Lambert acted quickly. Company executives complained to Dr. Gueriguian's

superiors, including Dr. Murray M. Lumpkin, Deputy Director of the FDA's Center for Drug Evaluation and Research (CDER). Shortly thereafter, Dr. Solomon Sobel, chief of the FDA's diabetes drug division, ordered Gueriguian's removal from the Rezulin review.

18. One FDA physician, who was involved in the "fast track" approval of Rezulin, elaborated on the events surrounding Gueriguian's removal in an interview with The Los Angeles Times: "Mac [Lumpkin] basically was hoping that the Gueriguian thing would go away and we could just kind of lose the review. . . . He [Lumpkin] just said that the Gueriguian review doesn't exist because it was in draft form and hadn't been finalized. . . Obviously, in hindsight, it should have been handled differently."

19. The Los Angeles Times further reported that, according to a number of sources, "before approving Rezulin, the FDA shared Gueriguian's review with Warner-Lambert and later purged the document from agency files."

20. Gueriguian was replaced by Dr. G. Alexander Fleming, an FDA team drug review leader. Fleming's medical review, as summarized in The Times, "noted that Warner-Lambert's clinical trials had identified 'significant safety issues' and that instances of liver injury 'suggested' unpredictable damage associated with Rezulin."

21. Fleming was assisted by Dr. Robert I. Misbin, a diabetes specialist, who was assigned to review the small-print language that would appear on Rezulin labels. One year later, Misbin would be faced with the task of reporting on deaths associated with Rezulin use.

22. On December 11, 1996, Fleming made a presentation to the FDA's Endocrinologic and Metabolic Drugs Advisory Committee. The Advisory Committee then voted 8 to 0 to recommend that the FDA approve Rezulin without any warnings about liver toxicity. Acting on the committee's recommendation, on January 29, 1997, the FDA approved Rezulin giving it "clearance for marketing".

23. However, three advisory committee members told The Los Angeles Times that they had never been told that 11 study participants had developed potentially life-threatening levels of liver toxicity and, as a consequence, had been taken off Rezulin, nor had they been told that Dr. Gueriguian had opposed the drug. The three panel members—Dr. D. Roger Illingworth, a metabolism and diabetes specialist at Oregon Health Sciences University in Portland; Dr. Jose Francisco Cara, a pediatric diabetes specialist in Detroit; and clinical pharmacist Colleen Colley with the Veterans Administration in Portland—all told The Los Angeles Times that they would have required liver-function monitoring as a condition of approval.

24. Two months later, in March 1997, Warner-Lambert began selling Rezulin. The drug's widely-publicized launch included a press release which claimed that Rezulin "is the first anti-diabetes drug designed to target insulin resistance." Warner-Lambert also represented that "Rezulin is the first anti-diabetes drug to work at the cellular level to improve insulin resistance directly enhancing the effects of circulating insulin. . . Until now other therapies lowered blood glucose by increasing insulin production or decreasing [liver] glucose output."

25. The launch prompted a quick response from the FDA. After reviewing the press release, the agency's drug-marketing and advertising division accused Warner-Lambert of making three "false and misleading" claims and recommended that Warner-Lambert "immediately discontinue" circulating the news release "and any other pieces containing the same or similar claims."

26. Warner-Lambert continued to aggressively publicize Rezulin in all media, including on the internet. The drug was touted by the company as a once-a-day pill for treating type 2 diabetes. Advertisements ran in Spanish as well as English to target the large Spanish-speaking diabetic population.

27. Among the misleading and deceptive claims made by Warner-Lambert were those which appeared in full-page, color magazine advertisements which described Rezulin as a drug with breakthrough effectiveness and "Side Effects Comparable to Placebo." A full-page ad making these claims ran in the May 1, 1997 edition of The New England Journal of Medicine.

28. The falsity of this claim is evidenced by Warner-Lambert's own clinical trial data which had been submitted to the FDA as part of the NDA. That data indicated that patients who had received Rezulin in clinical trials developed liver problems at four times the rate of controls who had received a placebo.

29. On August 4, 1997, the FDA broadened the approved uses of Rezulin. Rezulin could be used not only in combination with other Type 2 diabetes pills but also as a stand-alone or "mono" therapy.

30. Up until this point, Warner-Lambert had been successful in its efforts to keep the lid on serious and potentially life-threatening problems associated with Rezulin. By the fall of 1997, however, cases of serious liver injuries, including death after liver failure, in patients who had taken Rezulin began being reported to the FDA.

31. Dr. Misbin was placed in charge of evaluating the adverse event reports. At the time, he estimated that more than 12,000 Rezulin users would experience some liver injury. Misbin also advised his superiors that 2,000 of those patients might die unless their liver functions were closely monitored. In an interview published in the December 8, 1999 edition of The Los Angeles Times, Dr. Misbin elaborated: "I said to myself, 'At this very moment as I am writing this, there are 2,000 patients that are going to die of this drug unless we do something . . .' I mean, people were being treated with this drug and had no idea what was going on."

32. According to several news reports, including CBS News, Warner-Lambert had evidence of serious, and potentially life-threatening health problems, associated with Rezulin but had failed to inform the FDA. Specifically, CBS reported that in May 1997 Warner-Lambert had submitted documents to the FDA representing that none of the Rezulin trial participants had liver enzyme levels higher than "2 to 3 times . . . normal."

33. However, when Dr. Misbin subsequently investigated Warner-Lambert's representation, he found patients with liver enzymes far in excess of the levels reported by the company.

34. According to CBS News, "internal FDA documents show when Dr. Misbin raised the discrepancies, Warner-Lambert privately admitted its FDA report was 'not correct'."

35. Rezulin was allowed to remain on the market. However, the company was required to make the first of four safety label changes to Rezulin—each providing for closer monitoring of patients for elevated liver enzymes.

36. Citing "approximately 35 post-marketing reports of liver injury" in the U.S. and Japan,"[sic] the first label change was announced on November 3, 1997 and recommended liver enzyme testing routinely within the first one to two months, and every three months thereafter during the first year of treatment and periodically thereafter. The first label changes would not suffice and the next label change would come in less than one month.

37. News that Rezulin would soon be banned from sale in Great Britain reached the FDA. On November 26, 1997, Dr. Lumpkin spoke with an official at the British Medicines Control Agency about its imminent decision to ban further sales of Rezulin. The substance of that conversation was memorialized in an e-mail from Dr. Lumpkin to his boss, CDER Director Janet Woodcock, and six other FDA officials. As reported in the March 17, 2000 Los Angeles Times, the "impetus" for the decision was not the British drug regulatory agency but Glaxo-Wellcome, the company with rights to market Rezulin in Europe.

38. According to Lumpkin's e-mail, as paraphrased in The Los Angeles Times, "'[T]hey [Glaxo] no longer believed the risks outweighed the benefits' for at least two reasons: There was no way to predict which

Rezulin patients would be harmed, and the pace of liver injuries and deaths was by that point 'unacceptably high.'"

39. On March 22, 2000, faced with the incontrovertible statistics of a mounting death rate and documented cases of patients who were monitored in accordance with recommendations but still died of liver toxicity, Warner-Lambert agreed to withdraw Rezulin from the U.S. market.

40. Indeed, many safer and less expensive antidiabetic agents were available to patients being treated with Rezulin, both before and throughout the Class period.

41. Dr. Gueriguian summarized the Rezulin experience: "If [Rezulin] hadn't have been approved, at least 21 people would be alive now," he said. "In all probability, many more than that"

COUNT I

Negligence and Negligent Misrepresentation

42. The allegations contained in paragraphs 1 through 41 herein are hereby realleged and are fully incorporated herein.

43. Defendants owed a duty to consumers of Rezulin, including the Plaintiffs, to use reasonable care in designing, manufacturing, supplying, and selling Rezulin.

44. Defendants breached their duty of care, constituting negligence, as follows:

(a) Defendants failed to conduct adequate testing of the drug;

(b) Defendants failed to properly monitor and evaluate the drug's effect;

(c) Defendants concealed the clinical experience of the drug from the medical community, which included the medical personnel treating Plaintiffs;

(d) Defendants failed to fulfill the standard of care required of a reasonable, prudent pharmaceutical company engaged in the manufacture of a drug intended specifically for use by individuals suffering from diabetes;

(e) Defendants failed to adequately warn, of the dangers which it knew or should have known that the drug posed;

(f) Defendants failed to report adverse results of tests to the FDA, as required by law;

(g) Defendants placed the drug in commerce for sale and recommended its use to physicians without adequately warning physicians or other users of risks associated with the use of the drug;

(h) Defendants failed to properly market, advertise or distribute the drug, an inherently dangerous product, when they knew or should have known, that there existed dangers to users of Rezulin arising from the foreseeable and recommended use of the product;

(i) Defendants failed to disclose to the public, and to the Plaintiffs, in particular, facts relative to the drug being unsafe and a cause of dangerous side effects or complications; and

(j) Defendants failed to heed or further investigate adverse reaction reports submitted by

the medical community in order to determine whether the drug should be withdrawn from the market.

45. As a direct and proximate result of Plaintiff Troy Fisher's use of Rezulin, Plaintiff Troy Fisher suffered serious bodily injury and death, including but not limited to liver damage, renal damage, cardiac injury, cardiac/cardiovascular injury, significant weight gain and other physical and/or emotional injuries.

46. Defendants have, at all times material hereto, manufactured, promoted, sold, and distributed the drug in a manner which constituted gross, willful, malicious, reckless, and outrageous disregard for the consequences of its actions and omissions, including a criminal and culpable disregard for the consequences of its actions and omissions on the public.

47. Defendants had a duty to exercise reasonable care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Rezulin into the stream of commerce including a duty to:

(a) assure that the product did not cause users to suffer from unreasonable, dangerous side effects;

(b) warn of dangerous side effects; and

(c) disclose adverse material facts when making representations of facts to Plaintiffs.

48. Defendants failed to exercise reasonable care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Rezulin into the stream of commerce, because defendants knew or should have known that the use of this drug created

a high risk of unreasonable, dangerous side effects, including side effects such as, liver and heart failure, that can only be alleviated by liver transplant surgery or other invasive procedures and other side effects such as fatality.

49. Defendants breached their duty of reasonable care and duty to disclose material adverse facts to Plaintiffs by failing to use reasonable care in the design and manufacture of Rezulin so as to avoid liver toxicity; failing to provide sufficient accompanying warnings and/or indications concerning Rezulin and its health effects; failing to conduct adequate testing; and failing to ensure that Rezulin was used only in a manner for which it had been approved and which was safe.

50. Despite the fact that defendants knew or should have known that Rezulin caused unreasonable, dangerous side effects, defendants continued to market Rezulin to physicians and users, such as the Plaintiffs, when there were safer alternative treatments.

51. Defendants knew or should have known that Plaintiff Troy Fisher would foreseeably suffer injury as a result of defendants' failure to exercise reasonable care as described above.

52. Defendants intended that physicians and users, such as the Plaintiffs, rely upon their representations and statements and that physicians and users, such as the Plaintiff Troy Fisher, rely on defendants and their agents to inform them truthfully, accurately and fully about the serious adverse effects of Rezulin.

53. At the time of defendants' making of misrepresentations, misleading statements and/or omissions

about the safety of Rezulin, Plaintiffs were ignorant of their falsity. Plaintiffs relied upon defendants' superior knowledge and expertise and, justifiably, relied, to Plaintiffs' detriment, on defendants' representations and statements. Had Plaintiffs been aware of the true facts, Plaintiff Troy Fisher would not have purchased or used Rezulin.

54. By virtue of defendants' negligence and negligent misrepresentations, defendants have directly, foreseeably and proximately caused Plaintiffs to suffer serious bodily injury and death.

WHEREFORE, Plaintiffs respectfully request that this Honorable Court enter judgment against Defendants manufacturer in an amount that will fairly and adequately compensate Plaintiffs for their injuries, together with the costs of this action, interest, and attorney fees.

COUNT II

Fraud and Misrepresentation

55. The allegations contained in paragraphs 1 through 54 of this Complaint are realleged and are fully incorporated herein by this reference.

56. Defendants failed to publish adequate precautionary statements warning consumers as more information about adverse reactions became available. Defendants continued to design, manufacture and market the product. Defendants fervently promoted to physicians and consumers the beneficial and safe use of the drug.

57. The product warnings in effect were inadequate to alert prescribing physicians and patients of the actual risks associated with this drug that was then known to the defendants.

58. Plaintiff Troy Fisher's physician prescribed, and Plaintiff purchased and used Rezulin in reliance upon the express and implied representations of material facts made by defendants, Pfizer Inc., Warner-Lambert and Park Davis, and their agents directly and indirectly through uniform advertisements, sales literature and other forms of marketing.

59. Plaintiff Troy Fisher's physician prescribed, and Plaintiff made the decision to use Rezulin reasonably relying on defendants and their agents to disclose known defects and side effects of the drug. Defendants' representations, statements and concealment regarding material facts was made for the purpose of inducing Plaintiff and Plaintiffs physician to rely upon them and prescribe, purchase and use Rezulin.

60. Defendants knew or recklessly disregarded the fact that their statements regarding the safety of Rezulin were false, misleading, incomplete, and/or untrue when made.

61. The uniform misrepresentations, misleading statements, material omissions, and the fraudulent concealment of material facts by defendants or their agents were made with the intention to deceive and defraud or to conceal the truth about the unsafe nature of Rezulin.

62. The uniform misrepresentations, misleading statements, material omissions, and the fraudulent concealment of material facts by defendants or their agents were made to induce the prescription of Rezulin by Plaintiff's physician and the purchase and use of Rezulin by Plaintiff in order to increase sales and profits.

63. Plaintiffs and Plaintiff Troy Fisher's physician had no knowledge of the falsity or incompleteness of defendants' statements and representations when Plaintiff purchased the Rezulin manufactured, marketed, distributed, and sold by defendants or their agents.

64. Plaintiffs and Plaintiff Troy Fisher's physician had a right to and did rely on defendants' uniform statements and representations. Defendants' uniform statements and representations, express or implied, concerning the safety and effectiveness of Rezulin, were material to the decision to prescribe, purchase and use that drug, in that Plaintiff's physician would not have prescribed, and Plaintiff would not have purchased and used the drug if they had known that such statements and representations of defendants were false, misleading, incomplete, and untrue.

65. At all times during the course of dealing between defendants, Plaintiffs physician, and Plaintiffs, defendants failed to disclose adequately material adverse information regarding the dangerous side effects of Rezulin, as alleged above.

66. Defendants were under a duty to disclose the defective and unsafe nature of Rezulin to physicians and users, such as Plaintiffs. Defendants had sole access to material facts concerning the defect, and defendants knew that physicians and users, such as Plaintiffs, could not have reasonably discovered the defect.

67. Defendants' omissions were made deliberately, willfully and maliciously to mislead physicians and users, such as Plaintiffs, into justifiable reliance and action thereon, and to cause physicians to prescribe and consumers such as Plaintiffs to purchase and use

Rezulin and believe that the drug was safe and not defective.

68. Plaintiffs had no way to determine that defendants were making these material misrepresentations or fraudulently concealing material facts. Had defendants disclosed the material information regarding the unsafe and defective nature of Rezulin, Plaintiffs would have been aware of the defect and would not have purchased and used the drug or continued to believe that the drug was fit for its intended purpose.

69. By reason of defendants' fraudulent concealment, material misrepresentations, misleading statements, and/or material omissions, Plaintiffs was caused to suffer from Rezulin.

70. Because defendants' conduct in perpetrating the fraud described above was malicious, willful, wanton, and oppressive, or in reckless disregard of the rights of Plaintiffs, the imposition of exemplary damages against defendants is warranted.

71. As a result of defendants' fraud, Plaintiffs suffered serious bodily injury and death for which medical treatment was required and received.

72. As a direct and proximate result of Plaintiff Troy Fisher's use of Rezulin, Plaintiffs suffered serious bodily injury and death, including but not limited to liver damage, renal damage, cardiac injury, cardiac/cardiovascular injury, significant weight gain and/or other physical and/or emotional conditions.

WHEREFORE, Plaintiffs respectfully request that this Honorable Court enter judgment against Defendants manufacturer in an amount that will fairly and adequately compensate Plaintiffs for their

injuries, together with the costs of this action, interest, and attorney fees.

COUNT III

Breach of Express Warranty

73. The allegations contained in paragraphs 1 through 72 are realleged and are fully incorporated herein by this reference.

74. Defendants through description, affirmation of fact and promises relating to their drug products to the FDA, prescribing physicians and the general public, including the Plaintiffs herein, expressly warranted that Rezulin was both efficacious and safe for its intended use.

75. These warranties came in the form of: (i) publicly made written and verbal assurances of safety and efficacy by defendants pursuant to and following FDA approval, including but not limited to statements of clinical data that purported to report the incidence of adverse experiences with Rezulin, but which in fact grossly understated such incidence; (ii) press releases, interviews, and dissemination via the media of promotional information the sole purpose of which was to create demand for Rezulin, but which failed utterly to warn of the risks inherent to ingestion of Rezulin or the indications thereof; (iii) verbal assurances made by defendants' sales force to prescribing physicians of the safety and efficacy of defendants' anti-diabetes drug, and the downplaying of any indicia of risk associated with such drug; (iv) false and misleading written information, supplied by defendants, and published to Physicians.

76. Plaintiffs further alleges, that all of the aforementioned written materials are known to defen-

dants and in their possession, and it is Plaintiffs' reasonable belief that said materials shall be produced by defendants, Pfizer, Inc., Warner-Lambert and Parke Davis and be made of record once Plaintiffs are afforded the opportunity to conduct Discovery.

77. At the time of the making of these express warranties, defendants had knowledge of the purpose for which Rezulin was to be used and warranted it to be in all respects safe, effective and proper for such purpose.

78. Defendants themselves drafted the documents and/or made the statements upon which these express warranty claims are based, and in so doing, defined the terms of those warranties.

79. Rezulin does not conform to these express representations in that Rezulin is not safe and produces serious side effects, including life threatening liver injury.

80. As such, defendants' drug product was neither in conformity to the promises, descriptions or affirmations of fact made of this drug by the defendants, nor adequately contained, packaged, or labeled, or fit for the ordinary purposes for which such drugs are used.

WHEREFORE, Plaintiffs respectfully request that this Honorable Court enter judgment against Defendants manufacturer in an amount that will fairly and adequately compensate Plaintiffs for their injuries, together with the costs of this action, interest, and attorney fees.

COUNT IV

Loss of Consortium

81. The allegations contained in paragraphs 1 through 80 are realleged and are fully incorporated herein by this reference.

82. At all relevant times, Plaintiff Nancy Fisher was the lawfully wedded spouse of Plaintiff Troy Fisher.

83. As a proximate result of the negligence, breach of implied warranty, and breach of express warranty by Defendants manufacturer, Plaintiff Nancy Fisher suffered loss of consortium, loss of society and companionship, and other damages.

WHEREFORE, Plaintiffs respectfully request that this Honorable Court enter judgment against Defendants manufacturer in an amount that will fairly and adequately compensate Plaintiffs for their injuries, together with the costs of this action, interest, and attorney fees.

Respectfully submitted,

CHRISTOPHER S. VARJABEDIAN, P.C.

/s/ Vanessa G. Fluker
VANESSA G. FLUKER (P64780)
Attorney for Plaintiffs

Dated: December 18, 2003

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury on all issues so triable.

Respectfully submitted,

CHRISTOPHER S. VARJABEDIAN, P.C.

/s/ Vanessa G. Fluker
VANESSA G. FLUKER P64780
Attorney for Plaintiffs

Dated: December 18, 2003

SUPREME COURT OF THE UNITED STATES

No. 06-1498

WARNER-LAMBERT CO., LLC, *et al.*,
Petitioners,

v.

KIMBERLY KENT, *et al.*,

ON PETITION FOR A WRIT OF CERTIORARI to the United States Court of Appeals for the Second Circuit, No. 05-1705, 05-1743, 05-1745.

ON CONSIDERATION of the petition for a writ of certiorari herein to the United States Court of Appeals for the Second Circuit.

IT IS ORDERED by this Court that the said petition is granted. The brief of petitioners is to be filed with the Clerk and served upon opposing counsel on or before 2 p.m., Monday, November 5, 2007. The brief of respondents is to be filed with the Clerk and served upon opposing counsel on or before 2 p.m., Monday, December 3, 2007. A reply brief, if any, is to be filed with the Clerk and served upon opposing counsel on or before 2 p.m., Friday, December 28, 2007. Briefs of *amici curiae* are to be filed with the Clerk and served upon counsel for the parties on or before 2 p.m., 7 days after the brief for the party supported is filed, or if in support of neither party, within 7 days after the petitioners' brief is filed.

The Chief Justice took no part in the consideration or decision of this petition.

September 25, 2007

A true copy WILLIAM K. SUTER
Test:
Clerk of the Supreme Court of the United States
By _____
Deputy

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Supreme Court, U.S.
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No. 06-1498

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC AND PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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QUESTION PRESENTED

Michigan law shields manufacturers from product liability claims with respect to prescription drugs approved by the United States Food and Drug Administration ("FDA"). See Mich. Comp. Laws § 600.2946(5). This protection does not apply, however, and thus a claim may proceed if the fact-finder determines that the manufacturer-defendant:

> Intentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

Id. § 600.2946(5)(a).

Question presented:

Whether, under the implied preemption principles of *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), federal law preempts state law to the extent it permits or requires a fact-finder to speculate as to whether a defendant improperly disclosed information to the federal agency that materially affected the agency's decision to approve or not withdraw the drug.

PARTIES TO THE PROCEEDING

Petitioners, defendants-appellees below, are Warner-Lambert Company LLC and Pfizer Inc.

Warner-Lambert Company LLC is wholly owned by Pfizer Inc. Pfizer Inc. has no parent company, and no privately held company owns 10 percent or more of its stock.

Respondents, plaintiffs-appellants below, are the following 27 individuals:

Kimberly Kent, Personal Representative of the Estate of Virginia Kent

Emmett Kent

Connie Armstrong

Lauranane Bradley

Raymond Bradley, Sr.

Glenn Chandler

Billie Jo Flynt

Shelly Grotenhius

Judy Ann Hearn

Colleen Rose Herndon

Michael Herndon

Michael H. Kanakry

Mary Ann Kanakry

Julia Lynne Martin

Royal M. Martin

Janice L. Kimmel, Personal Representative of the Estate of Thea Martz

Mona Lorene Przytulski

David A. Rice, Personal Representative of the Estate of Robert Rice

Anita Louise Schultz

Richard P. Schultz

James Soukup, Personal Representative of the Estate of Barbara Soukup

Jennifer St. Pierre, Personal Representative of the Estate of Raymond St. Pierre

Donald R. Waun

Jean Waun

Linda Sherman

Stanley Sherman

Nancy Fisher, Individually and as Personal Representative of the Estate of Troy Fisher*

---

* Elizabeth M. Graham and Robert C. Graham, respondents at the time the petition for certiorari was filed, have since voluntarily dismissed their case. See *Graham* v. *Warner-Lambert*, Stipulation And Order Of Dismissal With Prejudice, No. 00cv2843 (LAK), Doc. No. 4779 (S.D.N.Y. ordered July 13, 2007; entered July 16, 2007).

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OPINIONS BELOW

The order of the court of appeals denying Warner-Lambert Company LLC and Pfizer Inc.'s petition for rehearing and for rehearing en banc was entered on February 12, 2007, is unreported, and is reprinted in the appendix to the petition for certiorari ("Pet. App.") at 39a-40a. The underlying order of the court of appeals was issued on October 5, 2006; an amended opinion was entered on January 18, 2007, is reported at 467 F.3d 85 (2d Cir. 2007), and is reproduced at Pet. App. 1a-28a. The order of the United States District Court for the Southern District of New York, and the transcript in which the district court set forth its reasoning, were entered on February 24, 2005, are unreported, and are reprinted at Pet. App. at 29a-38a.

JURISDICTION

The initial opinion of the court of appeals issued on October 5, 2006, and on January 18, 2007, the court entered an amended opinion modifying its decision. On February 12, 2007, the court of appeals denied rehearing. The petition for a writ of certiorari was filed on May 10, 2007, and was granted on September 25, 2007. JA 47-48. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1). Notification has been made under Rules 14.1(e)(v) and 29.4(c) of the Rules of this Court.

RELEVANT CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

The Supremacy Clause of the United States Constitution provides in pertinent part that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or

Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

Provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA") expressly invoked by the Michigan provision are 21 U.S.C. §§ 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395. Section 337(a) provides in relevant part that "all ... proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The text of the remaining pertinent provisions (*id.* §§ 332, 333, 334, 336, 337, 355, 372, 375(b), 393) is set forth in the Pet. App. at 43a-130a, or in the appendix hereto at 1a.

Pertinent regulations are Sections 10.30, 20.1, 314.50, 314.80, 314.81, 314.105, 314,125, and 314.150 of chapter 21 of the United States Code of Federal Regulation. The pertinent text of these provisions is set forth in the Pet. App. at 131a-192a, or in the appendix hereto at 2a-6a.

The pertinent provision of the Michigan statute in question, Mich. Comp. Laws § 600.2946(5), is set forth in the Pet. App. at 42a.

STATEMENT OF THE CASE

The Second Circuit's decision cannot be reconciled with this Court's holding in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, this Court held that federal law impliedly preempts plaintiffs' claims that a manufacturer was liable under state law for alleged misrepresentations made to FDA in violation of federal regulatory obligations governing the approval of medical products for marketing in the United States. *Id.* at

348. As this Court held, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Permitting a trier-of-fact to determine whether a manufacturer violated federally imposed duties to the agency—a relationship "inherently federal in character"—could not be squared with the role Congress delegated to FDA alone. *Id.* at 347-48.

Under the state-law provision at issue here, before a plaintiff's claims can be adjudicated, a fact-finder must determine that the manufacturer (i) "withh[eld] from or misrepresent[ed] to [FDA] information"; (ii) that was "required to be submitted under" the provisions of the federal statute FDA administers; and (iii) that the agency "would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a). Thus, the provision at issue here, like the claims in *Buckman*, impermissibly requires a trier-of-fact to intrude upon an exclusively federal domain and to decide matters that inevitably conflict with FDA's authority to police fraud-on-the-agency. As such, the provision is preempted; the Second Circuit's judgment should be reversed; the judgment of the district court should be restored and respondents' claims should be dismissed with prejudice.

A. Statutory Background

1. *Federal regulation of prescription drugs in the United States.* For more than a century, since the Pure Food and Drug Act of 1906, Congress has charged FDA, and its predecessor agencies, with regulating drugs in the United States. See generally John P. Swann, *History of the FDA*, *at* http://www.fda.gov/oc/history/historyoffda/default.htm. FDA's

responsibility has increased over time. In 1938, the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 *et seq.*), enhanced FDA's authority, and required "that an application be submitted to the FDA before any 'new drug' [could] be introduced into interstate commerce." *United States* v. *Generix Drug Corp.*, 460 U.S. 453, 458 (1983). The Drug Amendments of 1962 empowered FDA to evaluate not only safety, but also effectiveness. See Pub. L. No. 87-781, 76 Stat. 780 (1962).

At "[t]he heart" of the FDCA "is the grant of primary jurisdiction to FDA, the expert agency [Congress] created." *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). One of the FDCA's "core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); see 21 U.S.C. § 393(b)(2)(B). To this end, Congress charged FDA with "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). In making its determinations, FDA imposes a "strict and demanding" review. *Hynson*, 412 U.S. at 619.

Before a prescription drug can be marketed in the United States, the manufacturer typically must submit a New Drug Application ("NDA") to FDA that scientifically demonstrates the safety and efficacy of the drug for its intended use. See 21 U.S.C. § 355(b); 21 C.F.R. § 314.50 (detailing form and content of NDA). In this process, the FDCA and its regulations impose detailed federal disclosure obligations from the manufacturer to the agency. An NDA therefore must contain "full reports of investigations"

supporting safety and effectiveness, as well as submissions regarding the drug's components and composition; methods and controls used in manufacturing, processing, and packing the drug; and specimens of the warning labeling proposed to be used for the drug. 21 U.S.C. § 355(b)(1)(A)-(F). Federal law further requires the applicant to submit, and FDA to review, extensive analyses of clinical studies, pharmacological action, and toxicological effects of the drug. See 21 C.F.R. § 314.50(d).

Given the breadth of these requirements, a typical NDA spans many thousands of pages and is grounded in clinical trials that are conducted over many years.[1] In reviewing this extensive information, "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." *Id.* § 314.105(c). To that end, FDA reviews the NDA and ascertains whether it complies with federal disclosure requirements—and whether safety and efficacy have been proven to the agency's satisfaction. See generally 21 U.S.C. § 355(d) (grounds for denying NDA); 21 C.F.R. § 314.125 (same).

FDA typically spends well over a year evaluating NDA submissions and approves fewer than 100

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[1] *See, e.g.*, *Citizens Comm'n on Human Rights* v. *FDA*, 45 F.3d 1325, 1327 & n.4 (9th Cir. 1995) (NDA file of 300,000-400,000 pages); *Merix Pharm. Corp.* v. *GlaxoSmithKline Consumer Healthcare, L.P.*, No. 05 C 1403, 2006 WL 2931260, at *5 (N.D. Ill. Oct. 11, 2006) (NDA file of 175,000 pages); GAO, *New Drug Development, Report to Congressional Committees*, 26 Biotech. L. Rep. 82, app. 1 at 94 (2007) (underlying clinical trials average seven years to complete successfully).

NDAs a year.[2] The agency conducts a "comprehensive scientific evaluation of the product's risks and benefits under the conditions of use," not an "abstract" assessment. FDA, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).[3] During this time, FDA communicates with the company about "scientific, medical, and procedural issues that arise during the review process," ranging from "easily correctable deficiencies," to a "need for more data or information, or for technical changes," to "major scientific issues" that must be addressed before moving forward. See Ctr. for Drug Evaluation & Research ("CDER"), FDA, *CDER Handbook* 24 (1998), *available at* http://www.fda.gov/cder/handbook/handbook.pdf; see *id.* at 19 (chart of NDA review process).

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[2] *See* GAO, *supra*, at 86 (FDA took an average of 442 days to approve an NDA in 2002); CDER, FDA, *CDER Approval Times for Priority and Standard NDAs and BLAs Calendar Years 1993-2006* (2007), *available at* http://www.fda.gov/cder/rdmt/NDAapps93-06.htm (FDA approved 101 NDAs and "BLAs" (a similar process for biological products) in 2006: 21 priority track and 80 standard track; FDA approved 80 total in 2005); FDA, *New Drug Application Approvals and Receipts, Including New Molecular Entities, 1938 to Present*, *available at* http://www.fda.gov/oc/history/NDAapprovals.html (approving 22 new molecular entities in 2006, and 20 in 2005).

[3] *See* 21 C.F.R. § 314.50(d)(5)(viii) (NDA requires a "summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks *under the conditions stated* in the labeling") (emphasis added); *United States* v. *Rutherford*, 442 U.S. 544, 556-57 (1979) (recognizing that the balance between drug effectiveness and safety for approved drugs will vary depending on the condition for which medication is indicated).

Following its review, "FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c); see *id.* §§ 201.56(d), 201.57. Conversely, FDA "shall issue an order refusing to approve" the NDA if, in FDA's judgment, the submissions from the manufacturer "do not include adequate tests"; "the results of such tests show that such drug is unsafe for use" or "do not show that such drug is safe for use"; "there is a lack of substantial evidence that the drug will have the effect it purports"; or if the labeling "is false or misleading in any particular." 21 U.S.C. § 355(d). The agency may deny approval for a number of other reasons, including if FDA were to determine that the NDA "contains an untrue statement of a material fact." 21 C.F.R. § 314.125(b)(7).[4]

After approval, FDA continues to monitor approved drugs closely. See generally 21 U.S.C. § 355(k) (imposing postmarketing recordkeeping and reporting requirements on the manufacturer). For instance, the manufacturer must review and timely report to FDA "[a]ny adverse event associated with

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[4] FDA also may deny approval if, *inter alia*, it determines the methods and controls for the manufacturing, processing, and packing of the drug are inadequate to preserve its strength, quality, purity, and stability; the investigations "do not include adequate tests" to "show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling"; "[t]he results of the tests show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling or the results do not show that the drug product is safe for use under those conditions"; or "insufficient information about the drug" exists to determine whether it is "safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling." 21 C.F.R. § 314.125(b).

the use of a drug in humans, whether or not considered drug related," including events "occurring in the course of the use of a drug product in professional practice" and from overdose, abuse or withdrawal, as well as "any failure of expected pharmacological action." 21 C.F.R. § 314.80(a)-(c). The manufacturer must submit annual reports notifying the agency of any "significant new information ... that might affect the safety, effectiveness, or labeling of the drug," new clinical data, nonclinical laboratory studies, and status reports on postmarketing studies. See *id.* § 314.81(b)(2). Those reports must include scientific literature and postmarketing studies. *Id.* § 314.80(d)-(e). FDA also has informal mechanisms for assessing and reacting to postmarketing information. See generally Michelle Meadows, *Why Drugs Get Pulled Off the Market*, FDA Consumer, Jan.-Feb. 2002, *available at* http://www.fda.gov/fdac/features/2002/102_drug.html (discussing several examples of the agency's reaction to postmarketing information).

Congress recently further enhanced FDA's postmarketing powers in the Food and Drug Administration Amendments Act of 2007 ("FDAAA").[5] FDAAA grants FDA authority to require, *inter alia*, (i) additional post-approval studies or clinical trials, and (ii) new safety labeling changes on an expedited basis. Pub. L. No. 110-85, § 901, 121 Stat. 823, 922-43; see FDA, *Law Strengthens FDA*, *available at* http://www.fda.gov/oc/initiatives/advance/fdaaa.html ("This new law represents a very significant addition

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[5] *See* Pub. L. No. 110-85, 121 Stat. 823, 823 (2007) ("An Act to amend the [FDCA] ... to enhance the postmarket authorities of the [FDA] with respect to the safety of drugs, and for other purposes."); *id.* § 909, 121 Stat. at 950 (FDAAA "takes effect 180 days after the date of the enactment," *i.e.*, September 27, 2007).

to FDA authority."). FDAAA also, for example, expands a clinical trial data bank to make detailed information regarding the design, conduct, and results of drug trials publicly available through the Internet. See Pub. L. No. 110-85, § 801, 121 Stat. at 904-22. It further establishes an Advisory Committee on Risk Communication, "composed of experts on risk communication" as well as "representatives of patient, consumer, and health professional organizations" to facilitate disclosure of risk information. *Id.* § 917, 121 Stat. at 960.

In its review of postmarketing information, FDA "shall . . . withdraw approval" of a previously approved drug if the agency determines, among other things, that "scientific data show that such drug is unsafe for use" under the conditions of approval. 21 U.S.C. § 355(e). In addition, FDA may find withdrawal necessary if it determines, *inter alia*, that the company has "deliberately failed to maintain required records or to make required reports" under FDA standards; failed to explain the omission of certain information in agency submissions; or failed to comply with FDA standards in an "essential" study underlying the NDA such that the "validity of the study" is called into doubt. 21 C.F.R. § 314.150(b)(1), (6), (7).

In applying these standards, under the FDCA, "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA or its regulations. *Buckman*, 531 U.S. at 349 n.4; see *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357, 362 (2002) ("The FDCA invests [FDA] with the power to enforce its requirements."). Indeed, Section 337(a) expressly provides that "all . . . proceedings for the enforcement, or to restrain

violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

In exercising its enforcement prerogatives, FDA may examine drugs and investigate suspected fraud or misrepresentations by the manufacturer. *Id.* § 372. Should FDA find a problem, it has a range of options, including *in rem* forfeiture, injunction, and criminal prosecution against the responsible party if a "misbranded" drug is distributed in the United States market. See *id.* § 332(a) (injunctions); *id.* § 333 (criminal penalties); *id.* § 334(a) (seizure); and *id.* § 337(a) (enforcement proceedings); *Merrell Dow Pharms. Inc.* v. *Thompson*, 478 U.S. 804, 810-12 (1986); *id.* at 830 (Brennan, J., dissenting) ("Congress has provided the FDA with a wide-ranging arsenal of weapons to combat violations of the FDCA"). FDA has brought a number of enforcement actions in recent years and negotiated consent decrees that include disgorgement provisions ranging from $30-$500 million. See *United States* v. *Lane Labs-USA Inc.*, 427 F.3d 219, 234 (3d Cir. 2005) (citing examples).

Congress also has provided FDA with express statutory discretion to impose less stringent measures where the agency deems it appropriate. See 21 U.S.C. § 336 ("Nothing in [FDCA] shall be construed as requiring [FDA] to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever [FDA] believes that the public interest will be adequately served by a suitable written notice or warning.").[6] This Court has recognized that FDA has

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[6] *See also* 21 U.S.C. § 375(b) (FDA may "disseminate[] information . . . in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the

unreviewable discretion to decide how best to enforce the FDCA. See *Heckler* v. *Chaney*, 470 U.S. 821, 837-38 (1985) (FDA's decision not to take enforcement action is not subject to judicial review); see also *Brown & Williamson*, 529 U.S. at 181 (Breyer, J., dissenting) (FDCA should be interpreted in a manner that "both permits the FDA to take into account the realities of human behavior and allows it, in appropriate cases, to choose from its arsenal of statutory remedies").

FDA's regulations also provide a vehicle for citizens to report alleged violations, including fraud, to FDA and petition the agency to take regulatory or enforcement action. See 21 C.F.R. § 10.30 (allowing citizens to request that the agency "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action"); *Buckman*, 531 U.S. at 349.

2. *The Michigan Statute.* As part of state-law tort reform, the State of Michigan enacted legislation providing that:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller.

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consumer" and "collect[], report[], and illustrat[e] the results of the investigations of the Department"); Ernest Gellhorn, *Adverse Publicity by Administrative Agencies*, 86 Harv. L. Rev. 1380, 1408 (1973) (oftentimes "FDA ensures compliance by threatening seizure, injunction, and the issuance of publicity"; "publicity is usually the most potent persuader").

Mich. Comp. Laws § 600.2946(5); Pet. App. 3a.

At issue here is a companion provision of the Michigan statute withdrawing this defense if a plaintiff proves to the fact-finder that the manufacturer "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under the [FDCA]"—expressly invoking the provisions discussed above, see 21 U.S.C. §§ 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395—"and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a). Seven other States have enacted similar provisions.[7]

B. Respondents' Claims And The Proceedings Below

Respondents are 27 individual plaintiffs whose complaints assert product liability claims under Michigan law against petitioners based on allegations

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[7] Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(1) (creating a product liability defense for prescription drug companies unless the fact-finder determines the company "withheld from or misrepresented to [FDA] required information that was material and relevant to the performance of the product."); Ariz. Rev. Stat. § 12-701(B) (barring punitive damages against prescription drug company unless "the plaintiff proves, by clear and convincing evidence, that the defendant, either before or after making the drug available for public use, knowingly, in violation of applicable [FDA] regulations, withheld from or misrepresented to the administration information known to be material and relevant to the harm which the plaintiff allegedly suffered"); N.J. Stat. Ann. § 2A:58C-5(c) (same); N.D. Cent. Code § 32-03.2-11(6), (7)(a) (same); Ohio Rev. Code Ann. § 2307.80(C)(2) (same); Or. Rev. Stat. § 30.927(2) (same); Utah Code Ann. § 78-18-2(2) (same).

that they suffered personal injury from taking Rezulin (troglitazone), an FDA-approved prescription drug. See Pet. App. 332a-357a; JA 26-46.

1. Rezulin was indicated for the treatment of type 2 diabetes mellitus. Pet. App. at 336a, 343a, 353a, JA 32. "Type 2 diabetes is a life-threatening disease that affects 18 million Americans. It is a leading cause of coronary heart disease, blindness, kidney failure, and limb amputation." JA 27. FDA exercised regulatory oversight over Rezulin before and after approving it for marketing in the United States in 1997. See generally CDER, FDA, *Meeting No. 74 of Endocrinologic & Metabolic Drugs Advisory Committee* ("EMDAC") 38-49 (May 19, 2000), *available at* http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3615t1.pdf (discussing regulatory history) (excerpted in Exh. B to Pl. Fisher's Opp. to Mot. for Judgment on the Pleadings).

The NDA for Rezulin was submitted to FDA in July 1996. JA 27-28. "[B]ecause [Rezulin] was the first in a new class of products to treat what is widely recognized as a serious and life-threatening disease"—type 2 diabetes mellitus—FDA accorded it "priority review," EMDAC Tr. 43-44, a status "given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists," FDA, *Fast Track, Accelerated Approval and Priority Review* (May 2006), *available at* http://www.fda.gov/oashi/fast.html.[8]

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[8] Priority review makes "therapeutically important drugs available at an earlier time," but "do[es] not compromise the standards for the safety and effectiveness of the drugs" subject to this review because "additional FDA attention and resources" are employed. FDA, *Fast Track*, *supra*.

During review of the NDA, and before approving Rezulin for marketing in the United States, FDA recognized that liver and cardiovascular risks were associated with the drug. JA 29-30; Press Release, U.S. Dep't of Health & Human Servs. ("HHS"), Rezulin To Be Withdrawn from the Market (Mar. 21, 2000) (FDA stating that "[s]evere liver toxicity has been known to occur with Rezulin since 1997"). Nonetheless, following its review of the overall risk-benefit profile, EMDAC recommended approval of Rezulin. JA 31; EMDAC Tr. 43. In January 1997, FDA agreed and approved Rezulin for concomitant use with insulin or other anti-diabetic drugs; in August 1997, FDA broadened Rezulin's approval to include "stand alone" use. JA 31-32; EMDAC Tr. 43.

Thereafter, FDA continued to review reports of adverse liver-related effects in Rezulin patients. Between November 1997 and June 1999, Warner-Lambert agreed to a series of labeling changes regarding these issues. Pet. App. 6a-7a; EMDAC Tr. 44-45; accord HHS, *supra* ("[i]n consultation with FDA," Rezulin's manufacturer "strengthened the drug's labeling several times and has recommended close monitoring of liver function in patients taking Rezulin"). Following another EMDAC review of all of the science in March 1999, FDA concluded that concomitant use of Rezulin and insulin had benefits that outweighed risks, but monotherapy no longer had a "positive benefit to risk perspective." EMDAC Tr. 45-46; HHS, *supra*.

In March 2000, Warner-Lambert voluntarily withdrew Rezulin from the United States market. This action followed the introduction of two new drugs for the treatment of type 2 diabetes. FDA concluded that Rezulin had become "outmoded" and therefore "no longer [had] a positive benefit to risk

calculus, in the face of newer drugs [that] appear to have a better safety profile." EMDAC Tr. 82-83; HHS, *supra*.

At no time did FDA determine that petitioners had improperly withheld material information from the agency. Nor did FDA opine that any non-disclosure affected the agency's decisions about whether Rezulin should continue to be marketed.

2. After Rezulin was withdrawn from the market, respondents, all Michigan residents, filed product liability actions against petitioners. Those complaints were all filed in or removed to the United States District Court for the Eastern District of Michigan, which had diversity jurisdiction over the actions. Respondents each allege that they suffered personal injury from their use of Rezulin and that petitioners are liable under various product liability theories as a result. See Pet. App. 6a; *id.* at 332a-357a; JA 35-45. Most pertinent here, the complaints also allege that petitioners "knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market." Pet. App. 337a, 344a, 354a; see JA 33, 36, 43. There is no allegation that FDA *itself* ever determined that (i) petitioners violated federal law; (ii) petitioners improperly withheld information from FDA; or (iii) any purportedly withheld information would have affected, or later did affect, FDA's decisions about whether Rezulin could be marketed.

Following transfer of these cases by the Judicial Panel on Multidistrict Litigation to *In re: Rezulin Products Liability Litigation* (MDL No. 1348), before Judge Lewis Kaplan in the United States District Court for the Southern District of New York, petitioners moved for judgment on the pleadings.

Pet. App. 7a; see Fed. R. Civ. P. 12(c). In their motion, petitioners contended that Mich. Comp. Laws § 600.2946(5) provides a complete defense to respondents' claims. Petitioners further urged that respondents could not overcome petitioners' defense from product liability by availing themselves of Michigan's statutory exception for instances where a company "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under" the FDCA, and "the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a). Invoking *Garcia* v. *Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), in which the Sixth Circuit held this exception to be preempted, petitioners argued that this provision is preempted under *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

In their response, respondents did not dispute that, absent the exception of Mich. Comp. Laws § 600.2946(5)(a), the Michigan provision otherwise would provide a complete defense to petitioners from respondents' state-law claims. Respondents did not contend that FDA itself had found petitioners to have intentionally misrepresented or withheld material information required by the FDCA. Nor did they claim that the agency concluded that it would have denied or withdrawn Rezulin's approval if any allegedly withheld information had been disclosed. Rather, respondents contended simply that Mich. Comp. Laws § 600.2946(5)(a) was not preempted under *Buckman* and that *Garcia* had been wrongly decided.

3. Following *Buckman* and *Garcia*, the district court held that petitioners were entitled to judgment

on the pleadings. It concluded that the Michigan exception is preempted where, as here, the agency itself has made no finding of fraud. Pet. App. 32a-36a. Absent preemption, the district court reasoned, plaintiffs would be unfettered to "litigate claims of fraud on the FDA in individual personal injury suits," directly contrary to the decision in *Buckman*. *Id.* at 35a. The district court noted that this would lead to numerous harmful effects, including the potential for "FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again," and for FDA to "become the Food, Drug & Litigation Administration. The interference with the proper discharge of the mission that Congress created the FDA to perform would be enormous." *Id.* at 36a.

On appeal, the Second Circuit vacated the judgment entered by the district court. Pet. App. 1a-28a. Expressly parting with the analysis of the Sixth Circuit in *Garcia*, the Second Circuit held that the Michigan provision was not preempted because the Michigan plaintiffs were "not pressing 'fraud-on-the-FDA' claims" as in *Buckman*. *Id.* at 19a. Rather, it said that the plaintiffs were "asserting claims that sound in traditional state tort law." *Id.* The court acknowledged that the Michigan provision would require the trier-of-fact to find both that the manufacturer intentionally misrepresented material facts to FDA, and that FDA consequently would have denied or withdrawn approval of the drug had it been apprised of those facts. See *id.* at 19a-24a. The court further recognized that its approach would create "substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* courts." *Id.* at 25a. Nevertheless, the court concluded that *Buckman* is not applicable and held

that respondents' showing under § 600.2946(5)(a) is not preempted.

On May 10, 2007, petitioners timely filed a petition for a writ of certiorari, which was granted on September 25, 2007. JA 47-48.

SUMMARY OF ARGUMENT

The Second Circuit's decision cannot be reconciled with this Court's decision in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, this Court held that state-law claims based on an allegation that the company made fraudulent misrepresentations to FDA were preempted. *Id.* at 344-45. This Court further held that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Permitting a trier-of-fact to determine whether a company violated federally imposed duties to the agency—a relationship "inherently federal in character"—cannot be squared with the role Congress delegated to FDA alone. *Id.* at 347-48.

Furthermore, this Court held that there is no presumption against preemption given the quintessentially federal character of the relationship between the federal agency and a company navigating FDA's approval regime. *Id.* (holding that no federalism concern was implicated, and no presumption against preemption applies, where the regulated entity's "dealings with the FDA were prompted by [federal law], and the very subject matter of [the regulated entity's] statements were dictated by that [federal] statute's provisions"). This Court further observed that permitting state law to inject itself into this federal relationship would lead to several undesirable practical consequences.

First, it would disrupt the delicate balance of statutory objectives FDA must strike in exercising its own review of whether there has been fraud and, if so, what degree of reaction is warranted. *Id.* at 348-50. Such "flexibility is a critical component" of FDA's work given that the FDCA charges FDA with "pursu[ing] difficult (and often competing) objectives." *Id.* at 349; *id.* at 350 (recognizing the need for the agency to "police fraud consistently with the Administration's judgment and objectives"). Second, permitting such claims would "dramatically increase" the burdens on manufacturers seeking to comply with FDA's approval regime "in the shadow" of the inevitably differing standards of various state tort regimes and jury determinations, thereby skewing regulatory incentives. *Id.* at 350-51.

Third, the threat of state-law determinations would encourage companies "to submit a deluge of information that [FDA] neither wants nor needs," particularly in light of the significant volume of information FDA already is charged with reviewing. *Id.* at 351. This would burden FDA and distract it from its core mission of regulating potentially life-saving and beneficial medical treatments according to the detailed existing standards Congress has charged it with implementing. Given the practical public health considerations the agency must weigh, more information is not always better. See generally 71 Fed. Reg. at 3935 (explaining that "theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to 'lose its significance'" and "[o]verwarning, just like under-warning, can . . . have a negative effect on patient safety and public health").

The Michigan provision cannot be reconciled with *Buckman* because it requires a fact-finder to

determine the very same inherently federal issues the *Buckman* Court held to be off-limits. Under the Michigan provision, for plaintiffs' claims to survive, plaintiffs must prove—and the trier-of-fact must find—three facts that would impinge upon the agency's role: (i) that the company "[i]ntentionally withholds from or misrepresents to [FDA]"; (ii) "information concerning the drug that is required to be submitted" under the various FDCA provisions FDA administers; and (iii) that FDA either "would not have . . . approved" or "would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a). These inquiries intrude on the very same federal findings *Buckman* held to be solely within the agency's purview.

A State can choose to defer expressly to a federal regulatory scheme by shielding defendants from product liability claims when a matter is regulated by the Federal Government. What a State cannot do, however, is condition that defense on determinations by a fact-finder that intrude into an area of exclusive federal concern, *i.e.*, whether there has been "fraud-on-the-FDA." Because the Michigan provision trespasses on this area of exclusive federal concern, it is preempted.

ARGUMENT

I. FEDERAL LAW IMPLIEDLY PREEMPTS STATE LAW THAT REQUIRES THE FACT-FINDER TO DETERMINE WHETHER THE MANUFACTURER WITHHELD MATERIAL INFORMATION FROM THE AGENCY.

The Supremacy Clause of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land[,] . . .

any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Since *McCulloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819), "it has been settled that state law that conflicts with federal law is 'without effect,'" *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981)). These preemption principles apply equally whether the federal provision is a statute or a regulation; in either case, if the state law hinders or frustrates federal objectives, the state law is preempted. See, *e.g.*, *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 885 (2000); *Hillsborough County* v. *Automated Med. Labs. Inc.*, 471 U.S. 707, 713 (1985).

Federal law impliedly preempts state law when the state law either actually conflicts with a federal statute or regulation, frustrates accomplishment of the provision's objectives, or touches upon a field in which the Federal Government has asserted exclusive regulatory authority. *Cipollone*, 505 U.S. at 516. The categories of implied preemption are not "rigidly distinct," and "field pre-emption may be understood as a species of conflict pre-emption." *English* v. *General Elec. Co.*, 496 U.S. 72, 79 n.5 (1990).[9] Whether analyzed in terms of invading a narrow field of exclusive federal concern or in terms of posing an impermissible and inevitable conflict

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[9] *See, e.g.*, *Gade* v. *National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 104 n.2 (1992) (O'Connor, J., plurality opinion of four Justices) ("Although we have chosen to use the term 'conflict' pre-emption, we could as easily have stated that the promulgation of a federal safety and health standard 'pre-empts the field' for any . . . state law regulating the same safety and health issue."); *id.* at 115-16 (Souter, J., dissenting) (recognizing that conflict preemption may "present[] a situation similar in practical effect to that of federal occupation of a field") (internal quotation omitted).

with and obstacle to FDA's role in policing fraud in the regulatory regime it oversees, under the logic of *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Michigan fraud-on-the-FDA provision is impliedly preempted by federal law.

The Michigan provision impermissibly requires the trier-of-fact to place itself in the shoes of the expert agency, and to speculate as to whether FDA would have found the manufacturer violated a federal duty arising from the FDCA by intentionally withholding from or misrepresenting to the agency material facts about the safety and efficacy of the drug. The fact-finder then must speculate as to whether this alleged "fraud on the agency" also would have *caused* FDA to deny initial approval or withdraw existing approval of the drug, as opposed to taking a more limited enforcement response. These determinations are indistinguishable from those held to be impermissible in *Buckman*. They intrude upon an area of exclusive federal concern and would interpose state law as an impermissible obstacle to FDA's congressionally delegated obligation to make precisely these expert findings.

A. The Federal Government Has Exclusive Authority To Regulate Compliance With FDA Disclosure Requirements.

The field involving a company's obligation to provide appropriate information to the federal agency regulating it is one in which there is a longstanding and overriding federal presence, not one the States have traditionally occupied. In this uniquely and exclusively federal space, if the federal agency is to perform its congressional mission, the agency must be free to decide how best to obtain needed information as well as how to punish those it determines fail to comply.

1. Recognizing that FDA bears the "responsibility to police fraud consistently with [its] judgment and objectives," *Buckman* held that an attempt by a third-party to show that FDA had been defrauded would "*inevitably conflict*" with this federal domain. 531 U.S. at 350 (emphasis added); see *id.* at 348 (observing that a "delicate balance of statutory objectives" is implicated in FDA enforcement decisions). As *Buckman* explained, the regulatory regime governing medical product approval was established by federal legislation, and the duty of the manufacturer to the agency is strictly federal in character. Thus, it is only appropriate that the regime should be administered solely by federal officials, in accordance with federal standards. See *id.* at 347 ("the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law"). Put another way, because the FDCA "touch[es] a field in which the federal interest is so dominant"—*i.e.*, policing fraud against the federal agency—involving duties created by federal law and owed to a federal agency, "the federal system will be assumed to preclude enforcement of state laws on the same subject." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Federal law therefore preempts state law addressing the investigation and enforcement of a manufacturer's compliance with disclosure obligations during the FDA approval process. See *id.*; see also *Buckman*, 531 U.S. at 348-51; *Boyle* v. *United Techs. Corp.*, 487 U.S. 500, 505-06 (1988) (state law preempted where it sought to oversee duties owed to the Federal Government).

There is no role for States or private individuals to regulate a company's compliance with federal

disclosure requirements. Such matters are reserved to the federal agency. As detailed above, the FDCA empowers the agency alone to evaluate the sufficiency of submissions under the complex FDA regulatory scheme, to investigate suspected violations of disclosure requirements, 21 U.S.C. § 372, and to enforce those requirements as it sees fit. Central here, the FDCA vests enforcement power exclusively in the Federal Government: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." *Id.* § 337(a). Congress granted FDA a "variety of enforcement options to make a measured response"—ranging from administrative and civil penalties to seeking injunctive relief and criminal penalties. *Buckman*, 531 U.S. at 349; see 21 U.S.C. §§ 333, 336, 337.

Just as importantly, Congress has granted FDA discretion *not* to pursue formal enforcement measures after finding an FDCA violation. See 21 U.S.C. § 336; see also *Heckler*, 470 U.S. at 835 (FDA has "complete discretion . . . to decide how and when" to enforce the FDCA).[10] "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349.

Respondents' effort to prove fraud-on-the-FDA under the Michigan provision intrudes upon this

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[10] Although private citizens may report suspected regulatory violations to FDA and petition it to take action, 21 C.F.R. § 10.30—and although Congress did grant state officials limited rights to bring suit to enforce certain prohibitions on misbranded *food*, 21 U.S.C. § 337(b)—nowhere does the federal statutory or regulatory scheme contemplate that private or state actors may enforce a drug manufacturer's compliance with federal disclosure obligations. *See Buckman*, 531 U.S. at 349.

field. It is thus preempted. In making their showing, respondents must prove that the manufacturer "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under the [FDCA]" and that "the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information [had been] accurately submitted." Mich. Comp. Laws § 600.2946(5)(a).

Thus, necessary to a determination that this exception applies are findings that (1) federal law required the manufacturer to disclose certain information to the agency, (2) the manufacturer failed to produce that information to the agency, and (3) the failure to disclose was material to the agency's approval of the drug. See *id.*; *Garcia*, 385 F.3d at 964-66. Each one of these findings involves the state fact-finder in the interpretation and application of federal statutes and regulations that are, by congressional directive, subject exclusively to federal oversight. See Mich. Comp. Laws § 600.2946(5)(a) (citing, *inter alia*, 21 U.S.C. §§ 355-360); cf. 21 U.S.C. § 337(a).

Unlike the state laws at issue in cases in which this Court has declined to find preemption, the Michigan provision at issue here does not regulate public health and safety. Rather, it trespasses directly on an area of exclusive federal concern. See Mich. Comp. Laws § 600.2946(5)(a); cf., *e.g.*, *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) (state law allowed persons injured by nuclear incidents to recover from operators).[11] The only effect of this

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[11] As *Buckman* explained, *Silkwood* is readily distinguishable. First, nowhere did the state law at issue in *Silkwood* require the plaintiff to demonstrate that *federal* duties had been violated to

provision is to police and enforce compliance with FDA disclosure rules. See *Garcia*, 385 F.3d at 966. But this is not a valid role for state legislation: investigating and enforcing compliance with FDA regulations concerning disclosures to FDA is (and always has been) a matter of exclusive federal concern. *Buckman*, 531 U.S. at 347-53; *Kobar ex rel. Kobar* v. *Novartis Corp.*, 378 F. Supp. 2d 1166, 1173 (D. Ariz. 2005) (both the common law fraud-on-the-FDA claim at issue in *Buckman*, and a state statute that requires plaintiffs to prove fraud-on-the-FDA to avoid a bar on punitive damages, "place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process").

2. The problems that would flow from a contrary conclusion, under which state juries would be allowed to judge a manufacturer's compliance with disclosure obligations to FDA, are manifest. Interpretation of agency rules concerning such disclosures, which often hinge on application of specialized scientific and public health knowledge, would be entrusted not to the expert agency alone but to independent lay fact-finders in the different States. *Buckman*, 531 U.S. at 350-51. A manufacturer could no longer be certain

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proceed with her claims. *See Buckman*, 531 U.S. at 352 (inquiry in *Silkwood* "was not based on any sort of fraud-on-the-agency theory"). Here, in contrast, the fact-finder is required to find a violation of a federal duty owed to the agency alone and then to further determine how the agency would have reacted to the violation. *See* Mich. Comp. Laws § 600.2946(5)(a). Second, the federal regime at issue in *Silkwood* contained no provision comparable to Section 337(a), which provides "clear evidence" that the FDCA is to be "enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352.

that adherence to the agency's interpretations concerning its own regulations about disclosures to that agency would guarantee a finding of compliance with those regulations. *Id.* To defend against a determination of non-compliance by a lay fact-finder—better ensuring its prospects of prevailing in eventual litigation through motions practice or at trial—the manufacturer would have a substantial incentive to submit as much information as possible to the agency. See *id.* at 351.[12] When a fact-finder is permitted to determine what *should have* been submitted to an agency and what the agency *might have* found material--as the Michigan provision requires—the party interacting with the agency would "have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA[]." *Id.*

Moreover, instead of agency officials having final word on a manufacturer's compliance with FDCA-imposed duties concerning disclosures to FDA—and whether, even in the face of noncompliance, the scientific data nonetheless support keeping the drug on the market—lay jurors nationwide would be permitted to make shadow determinations on these sensitive issues. The force of the agency's expertise, in turn, would be diminished and Congress's interest

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[12] The Second Circuit acknowledged as much. *See* Pet. App. 25a ("So long as a court or jury is *allowed to consider* evidence of fraud against the FDA . . there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* Courts."). Nevertheless, it opined that "the incentive to flood the FDA appreciably escalate[s]" "[o]nly when proof of fraud is by itself *sufficient* to impose liability." *Id.* To the contrary, the incentive will exist whenever a fact-finder is required to make the same determination FDA must make.

in uniform drug regulation would be undermined, if States could impose liability whenever they deem that a drug's withdrawal would have been appropriate because of perceived fraud-on-the-agency.

This problem is particularly acute in the context presented here, in which the agency already is charged with analyzing detailed information it considers important and rendering sensitive public health judgments. In this highly regulated context, more is not necessarily better. Instead, additional state-law requirements for the disclosure of information to the federal agency can erode and disrupt the careful assessment the expert agency already is required to make.

Moreover, to retain any semblance of a uniform national scheme of drug regulation, FDA would be forced to monitor, assess, and possibly engage in a multitude of lawsuits across the country. FDA consistently might feel (or be) compelled to make its officials available to testify in litigation proceedings to refute improper speculation about whether (i) data had been misrepresented or withheld by a manufacturer, (ii) the manufacturer even had a federal duty to disclose such data, and (iii) the agency would have declined or withdrawn approval of the drug even if a federal duty had been violated. FDA would become, in the words of the district court, the "Food, Drug & Litigation Administration" with litigation burdens creating "enormous" interference with the agency's functions. Pet. App. 35a-36a.

It is inconceivable that Congress intended these results. To the contrary, the statutory scheme demonstrates conclusively that Congress anticipated that only federal officials would have authority to investigate and enforce federal regulations concerning required disclosures to the FDA. 21

U.S.C. §§ 337(a), 336; cf. *Cipollone*, 505 U.S. at 516 ("[t]he purpose of Congress is the ultimate touchstone" in a preemption analysis) (internal quotation omitted). Because the Michigan fraud-on-the-FDA provision requires a fact-finder to decide whether a manufacturer complied with disclosure requirements to FDA, and whether that mattered to FDA's approval, it intrudes on a field committed exclusively to federal control. It is, therefore, preempted. See *Buckman*, 531 U.S. at 350-51.

B. The FDCA Regime Designed By Congress Would Be Unconstitutionally Obstructed If Fact-Finders Were Allowed To Make The Determinations Required By Michigan's Exception To Its Statutory Bar To Product Liability.

The fraud-on-the-FDA determination required by the Michigan provision also conflicts with, and poses an impermissible obstacle to, FDA's uniform enforcement of the FDCA. This Court has recognized that "even if Congress has not occupied the field, state law is naturally preempted to the extent of any conflict with a federal statute." *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372 (2000). Implied conflict preemption exists both where it would be impossible for a party to comply with both state and federal law, and "where 'under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at 372-73 (alterations omitted) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)).

As shown above, through the FDCA, Congress has delegated to FDA the power to determine whether prescription drugs are sufficiently safe and effective

to be marketed in the United States, and to remain on the market. *Supra* at 3-11; see also *Brown & Williamson Tobacco Corp.*, 529 U.S. at 165 (Breyer, J., dissenting) (endorsing view that FDCA "'is a purposefully broad delegation of discretionary powers by Congress'"). Central determinations within FDA's purview are whether a manufacturer has satisfied pre- and post-market disclosure requirements. See, *e.g.*, 21 U.S.C. § 355(e), (k); 21 C.F.R. § 314.50.

FDA never found that petitioners failed to comply with pre- or postmarketing disclosure requirements regarding Rezulin. Moreover, FDA never withdrew approval for the marketing of Rezulin in the United States based on any failure of disclosure by petitioners. Yet respondents cannot recover under the Michigan statute unless they could prove, and the trier-of-fact were to find, exactly the opposite. See Mich. Comp. Laws § 600.2946(5)(a). To allow the trier-of-fact to make these determinations would intrude on, and interfere with, FDA's core functions as delegated by Congress. Because the Michigan statutory exception requires the trier-of-fact to reach determinations "intimately blended and intertwined with the responsibilities of the national government," state law "'must yield'" to the expert federal agency acting on the same subject under the congressional design. *Hines*, 312 U.S. at 66 (quoting *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824)).

1. In *Buckman*, this Court held that attempts to prove FDA was defrauded "conflict with, and are therefore impliedly pre-empted by, federal law." 531 U.S. at 348. There, the plaintiffs attempted to show that they had been injured by the fraudulent conduct of a consultant the manufacturer had retained to assist it in obtaining FDA approval to market a medical product. The plaintiffs argued that had the

consultant not defrauded FDA during the approval process, the product causing their injury never would have come to market. As discussed, the *Buckman* Court concluded that policing fraud on federal agencies is a function reserved to the Federal Government, and was delegated to FDA in the FDCA context. See *id.* at 347-48. Recognizing that the agency itself bears the "responsibility to police fraud consistently with [its] judgment and objectives," the opinion made clear that any attempted showing by a third-party that FDA had been defrauded would upset the "delicate balance of statutory objectives" implicated in FDA decisionmaking under the FDCA. *Id.* at 348, 350.

Indeed, the likelihood of conflict preemption is increased whenever a plaintiff seeks to have lay fact-finders reformulate through state law the technical balances reached by federal agencies. See, *e.g.*, *Geier*, 529 U.S. at 877-82 (holding obstacle preemption applies where Department of Transportation applied its expertise and considered delicate balance of regulatory issues); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691, 714 (1984) (holding preemption applies where Federal Communications Commission "attempted to strike a balance" among regulatory concerns in serving an "important and substantial federal interest"); *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151, 177 (1978) (holding preemption applies where congressional scheme evidenced desire to have regulation set by the Secretary of Transportation who had "an overview of all the possible ramifications" and "act[ed] only after balancing all of the competing interests"); cf. *Leslie Miller, Inc.* v. *Arkansas*, 352 U.S. 187, 190 (1956) (per curiam) (state's exercise of "virtual power of review" over federal determinations would frustrate congressional intent).

A contrary approach would lead to numerous undesirable practical consequences detailed above. First, it would disrupt FDA in determining whether a violation has occurred and, if so, the proper level of response (if any). *Buckman*, 531 U.S. at 348-50. Second, it would "dramatically increase" the burdens on manufacturers endeavoring to comply with federal standards in the shadow of competing and inconsistent state-law demands as to that very same federal system. *Id.* at 350-51. Third, pressures from these shadow regimes would encourage companies "to submit a deluge of information that [FDA] neither wants nor needs." *Id.* at 351. Additionally, FDA would be distracted from its congressional mission by inevitable efforts by courts and private parties to supplant federal regulatory processes by having FDA address allegations of fraud in the context of ongoing private litigation. These overlapping and inconsistent state-law pressures distort the expert agency making these determinations on its own terms according to its own regulatory priorities, as is the intention of the federal drug regime.

2. These principles apply forcefully, and dispositively, here. For a plaintiff to satisfy Michigan's statutory exception, his or her claims require the fact-finder to make precisely the determinations found preempted in *Buckman*. Before the plaintiff is allowed to prove his or her case—by establishing a tort claim—he or she bears the burden of convincing a fact-finder that FDA was materially defrauded by the defendant. See Mich. Comp. Laws § 600.2946(5)(a). This showing is not remotely akin to proving a "traditional" state-law fraud claim involving private parties to a dispute. Whether the allegedly withheld materials should have been disclosed to FDA is not determined vis-à-vis the

relationship between plaintiff and defendant. Rather, just as in *Buckman*, plaintiffs must show that the manufacturer or other regulated entity violated a *federal duty* by withholding or misrepresenting the information in question (*i.e.*, information "required to be submitted under the federal food, drug, and cosmetic act") to the federal agency. Cf. *Boyle*, 487 U.S. at 505-06 (holding that state law was preempted where it sought to oversee duties owed to the Federal Government).

Moreover, the Michigan statute requires the same speculation about proximate cause that was held to be impermissible in *Buckman*. That is, the fact-finder must determine that, had the information not been misrepresented or withheld, then *FDA* would have taken one of two specific actions: (i) denied approval, or (ii) withdrawn approval. But permitting a fact-finder to speculate whether disclosure of the misrepresented information would have led to denial or withdrawal of the NDA is a frontal attack on FDA's authority that cannot be reconciled with Congress's charge. The fact-finder essentially would be required to determine either that FDA (i) never should have approved the drug, or (ii) should have removed it from the market earlier, because of allegedly fraudulent disclosures to the agency. But, it is axiomatic that "one of the [FDCA]'s core objectives" was to delegate these determinations exclusively to FDA. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 133; see 21 U.S.C. § 337(a); *Hynson, Westcott & Dunning*, 412 U.S. at 627 (Congress created FDA as the "expert agency" to regulate drugs).

Lay jurors necessarily lack the scientific expertise and perspective FDA draws upon. They simply cannot reliably assess whether FDA would have

disapproved an NDA or withdrawn a drug's approval because of alleged fraud-on-the-agency. Cf. *Heckler*, 470 U.S. at 831 (agency's decision not to enforce generally is "unsuitabl[e]" for judicial review because it "often involves a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise"). Yet if the fact-finder were to reach these conclusions, the defendant would be exposed to inappropriate and potentially massive liability. Such liability could even have the potential to drive a product off the market, although FDA would not want that result.

Furthermore, there are reasons to believe that lay persons would speculate inaccurately that FDA would select its most severe enforcement measures from the panoply of options available in its arsenal to combat fraud, even though the agency might not do so. See *Buckman*, 531 U.S. at 349-50; 21 U.S.C. § 336 (granting agency discretion to bypass formal enforcement actions "whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning"); see also, *e.g.*, *A.L. Pharma, Inc.* v. *Shalala*, 62 F.3d 1484 (D.C. Cir. 1995) (upholding FDA's discretionary decision not to withdraw drug approval as penalty for misrepresentation). Specifically, a jury that already has determined that a defendant "intentionally misrepresented or withheld" required information may be predisposed to overestimate the gravity of the information in question. That is, the jury's reaction to the perceived misconduct may cause it to conclude—wrongly—that FDA's enforcement would have been drastic because the fact-finder necessarily lacks perspective beyond the individual patient alleged to have been injured in the case before them. See generally *Carroll* v. *Otis Elevator Co.*, 896 F.2d

210, 215-16 (7th Cir. 1990) (Easterbrook, J., concurring) (recognizing the tendency of jurors in product liability cases to focus on "today's injury" rather than probabilities, thus rendering "invisible" the individuals who would have been harmed had the allegedly defective product not been on the market). FDA, by contrast, (i) is keenly aware of the scores of patients for whom the drug has been successful, thus allowing the agency to make an overall public health risk-benefit calculation that may be lost on the lay jury in a lone case, and (ii) when considering whether an NDA should be denied or withdrawn must weigh certain individual patients experiencing side effects against the overall public health risks and benefits of alternative therapies or having no potentially viable treatment available. In short, the jury's perspectives on the propriety of approval or withdrawal can be overwhelmingly shaped by a response to the exigencies in a single case. Pursuant to Congress's command, however, FDA must consider the overall public health.[13]

In sum, permitting a fact-finder to determine, through lay speculation, (i) whether certain data was "required to be submitted under" the FDCA regime

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[13] Absent these protections, it is relatively easy for plaintiffs' counsel to capitalize on perceived defects in a manufacturer's submissions to FDA to create jury hostility. Plaintiffs can seize on stray documents that were not submitted—even where FDA was fully apprised of an issue or would not have viewed the unsubmitted documents as material. Yet it is extremely difficult for a manufacturer to prove a negative, that is, that FDA was *not* defrauded. Making such a showing is particularly difficult given FDA's understandable reluctance to expose its officials to testifying in tort litigation. *See* 21 C.F.R. § 20.1; *Giza* v. *Secretary of Health, Educ. & Welfare*, 628 F.2d 748, 750-52 (1st Cir. 1980) (affirming refusal to compel testimony of FDA official in product liability action).

and (ii) whether FDA would have denied or withdrawn approval of the drug had the information been presented differently, are the very inquiries foreclosed by *Buckman* because they would present severe obstacles to the agency appropriately accomplishing its regulatory function.

3. Nothing in the concurring opinion in *Buckman* would lead to a different result here. That opinion suggested that the preemption principles discussed here may be diminished "if, prior to the instant litigation, [1] *the FDA had determined* that petitioner had committed fraud [on the agency] *and* [2] had then taken the necessary steps to remove the harm-causing product from the market." 531 U.S. at 354 (Stevens, J. and Thomas, J., concurring in the judgment) (emphasis added). Where "FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market," the concurrence posited, state claims would supplement, not encroach upon, the federal regulatory scheme. *Id.* Cf. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 492-502 (1996) (allowing, in the absence of express or field preemption, state-law tort claims to proceed where they paralleled federal law); *Garcia*, 385 F.3d at 966 ("[T]he same concerns" of inter-branch meddling that animated *Buckman* "do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process.").

In this case, however, FDA did not find that petitioners have committed fraud-on-the-agency, let alone announce that it was withdrawing drug approval or that it never would have approved the NDA in the first instance on account of such fraud. Indeed, respondents have never claimed—either in their complaints, or in their opposition to petitioners'

motion for judgment on the pleadings, or in their responses to the Second Circuit, or their opposition to the petition for certiorari in this Court—that FDA itself found petitioners had committed fraud-on-the-agency. Because the rule endorsed by the concurring Justices in *Buckman* therefore has no bearing here and would provide no relief to respondents in the present case, this Court need not address such a potential exception to preemption. Accordingly, should this Court hold that Michigan's statutory exception is preempted as applied here, it need not remand this case for further proceedings. Rather, the Second Circuit should be reversed, and the judgment of the district court reinstated.

II. THE SECOND CIRCUIT'S ANALYSIS IS FLAWED AND IRRECONCILABLE WITH *BUCKMAN*.

Although the opinion of the court of appeals below points to a number of distinctions between the circumstances here and in *Buckman*, none makes a difference to the core point in both cases: lay juries are not entitled to adjudicate whether there has been a material fraud-on-the-federal agency.

The court of appeals gave three inter-related, and purportedly "crucial," distinctions for avoiding *Buckman* preemption here. See Pet. App. 18a. First, it framed its analysis with a "presumption against preemption" because it viewed this case as involving ordinary and traditional State health and safety considerations, rather than an inherently federal question. *Id.* at 18a-19a. Second, the Second Circuit considered it significant that respondents bring underlying "traditional" common law tort claims premised on petitioners owing a duty to them, whereas in *Buckman* the fraud-on-the-FDA claim rested on a duty from the company to the agency

alone. *Id.* at 19a-23a. Third, the court opined that there was a meaningful distinction between proof of fraud-on-the-agency as a cause of action (the setting in *Buckman*) versus proof of fraud-on-the-agency to rebut an affirmative defense (as it framed the issue here). *Id.* at 23a-24a. These distinctions, all versions of the same essential point, collapse under a single analytic flaw: they ignore the impermissible federal-law inquiry that is inevitably required by the Michigan provision.

A. There Is No Presumption Against Preemption In This Context.

This Court in *Buckman* already conclusively held that there is no presumption against preemption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Buckman*, 531 U.S. at 347 (quoting *Rice*, 331 U.S. at 230); see § I, *supra*. Nonetheless, the Second Circuit opinion places an impermissible "thumb on the scale" by framing respondents' claims as simply invoking the traditional "province of the states to safeguard the health and safety of their citizens," rather than a federal issue. Pet. App. 2a; see *id.* at 3a (describing common law liability as "the bedrock of state regulation"); *id.* at 18a-19a. This is wrong for at least two reasons.[14]

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[14] Even if a presumption against preemption applied—and it does not—the uniquely federal circumstances at issue here still would overcome any such presumption and compel preemption. *See, e.g.*, *Ray*, 435 U.S. at 157, 160, 163-64 (holding that, notwithstanding the application of a presumption against preemption, state-law requirements for vessels were preempted by federal law given the federal character of the relationship at issue (between vessels and the Coast Guard)).

1. The Michigan provision at issue here does not "regulate health and safety." To the contrary, it purports to regulate, as a matter of state law, a strictly federal matter: a company's compliance with federal disclosure standards under the FDCA that FDA alone is empowered to enforce. *Buckman* held that there is no presumption against preemption where a lay jury is asked to determine whether there has been a material fraud against a federal agency. This follows because the manufacturer's relationship with the agency under the federal scheme is "inherently federal in character" and "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Buckman*, 531 U.S. at 347 (quoting *Rice*, 331 U.S. at 230).

The Second Circuit, however, held that, because the Michigan provision "cannot reasonably be characterized as a [S]tate's attempt to police fraud against the FDA," but was passed as part of an effort to "'regulat[e] matters of health and safety,'" a presumption against preemption applied. Pet. App. 18a-19a. To the contrary, the very premise of the underlying Michigan provision shielding drug manufacturers from product liability claims is to defer expressly to the Federal Government's unique role in regulating highly specialized medical products. In any event, the court below cited no authority holding that a presumption against preemption is assessed by the supposed *purposes* rather than by the *operation and effect* of the state-law provision at issue. In fact, the actual function of the provision is what matters. Cf., *e.g.*, *American Ins. Ass'n* v. *Garamendi*, 539 U.S. 396, 418 (2003) (examining the *effect* of state law on the federal interest); *Egelhoff* v. *Egelhoff ex rel. Breiner*, 532 U.S. 141, 147 (2001) (same).

Even if the Second Circuit were correct to analyze the purposes of the Michigan fraud-on-the-FDA provision in the abstract rather than the practical effect of the exception at issue here, it impermissibly ignores that the exception requires that the fact-finder engage in the same analysis found impermissible in *Buckman*. In doing so, the trier is required to determine issues "inherently federal in character"—namely, whether the defendant's "dealings with the FDA [which] where prompted by the [FDCA], and the very subject matter of [defendant's] statements [which] were dictated by that statute's provisions" violated *federal law*. *Buckman*, 531 U.S. at 347-48.

2. Although the Court need not look beyond the clear holding of *Buckman* to determine that no presumption against preemption applies in this context, there is yet another reason why the Second Circuit's presumption is wrong. No presumption against preemption applies where, as here, the state law stands as an obstacle to a federal scheme.

This notion is particularly striking in the context present here, because state law is seeking to regulate an area in which there has been "a history of significant federal presence." *United States* v. *Locke*, 529 U.S. 89, 108, 111 (2000) (citing *Rice*, 331 U.S. at 230). For more than a century, the Federal Government has regulated drugs in the United States market. See generally *United States* v. *Walsh*, 331 U.S. 432, 434 (1947) ("[t]he [FDCA] rests upon the constitutional power resident in Congress to regulate interstate commerce" and Congress has regulated drugs "[t]o the end that the public health and safety might be advanced") (citing Article 1, § 8, cl. 3).

When a field has long been subject to federal control, "there is no beginning assumption that

concurrent regulation by the State is a valid exercise of its police powers." *Locke*, 529 U.S. at 108; see *Buckman*, 531 U.S. at 347. In such a circumstance, "one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict" between federal and state law. *Geier*, 529 U.S. at 885; see *Felder* v. *Casey*, 487 U.S. 131, 138 (1988) ("Under the Supremacy Clause of the Federal Constitution, '[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'") (citations omitted).[15]

B. There Is No Meaningful Difference Between The Inquiry At Issue Here And In *Buckman*.

The Second Circuit also distinguished *Buckman* on the basis that respondents "assert[] claims that sound in traditional state tort law" and thus involve duties owed by the manufacturer to respondents, see Pet. App. 19a-20a, whereas, in *Buckman*, the plaintiffs sought to recover based on violation of a duty owed to FDA alone, *id.* at 20a. The court below also posited that in a pure FDA-fraud case (*Buckman*), "proof of fraud against the FDA is *alone sufficient* to impose

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[15] Notwithstanding some general debate about whether a presumption against preemption applies in the implied preemption context, *see generally Crosby*, 530 U.S. at 374 n.8 (declining to resolve whether a presumption against preemption applied in the context of implied conflict preemption); *see also Engine Mfrs. Ass'n* v. *South Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004) (recognizing "not all Members of this Court agree" about the role of the "'presumption against preemption'"), at a minimum, there is no role for such a presumption as to the quintessentially federal inquiry at issue in this case.

liability," but here respondents' "traditional" tort claims required them to make out "freestanding allegations of wrongdoing." *Id.* at 20a-21a. This wooden interpretation of *Buckman* improperly elevates form over function and disregards the effect of the pertinent federal law inquiry in both circumstances.

1. Contrary to the Second Circuit's view, it makes no difference to the analysis that the claims in this case find their "'vintage'" in traditional tort law. See Pet. App. 20a. That respondents ultimately must prove a violation of a manufacturer's traditional state-law duty to prevail on their claims does not obviate the fact that to be *permitted* to proceed under Michigan's product liability law respondents must prove a violation of "a newly-concocted duty between a manufacturer and a federal agency." *Id.*; see Mich. Comp. Laws § 600.2946(5)(a). Accordingly, as in *Buckman*, respondents' recovery irreducibly depends on proving to a state fact-finder that petitioners materially violated federal requirements. See 531 U.S. at 348-49; *id.* at 352-53; *Garcia*, 385 F.3d at 966 ("'state tort remedies *requiring* proof of fraud committed against the FDA are foreclosed since federal law preempts such claims'") (quoting district court).

As noted, the Michigan statute amended Michigan's earlier common law product liability regime by interposing a general defense to product liability for manufacturers, and creating a limited exception when the manufacturer is shown to have committed fraud-on-the-FDA during the drug approval process. Mich. Comp. Laws § 600.2946(5); *Taylor* v. *SmithKline Beecham Corp.*, 658 N.W.2d 127, 130-31 (Mich. 2003). By so doing, this amendment in effect created the necessary pathway to relief for plaintiffs,

requiring proof both that the product was defective *and* that the manufacturer had violated FDA disclosure rules. See *Garcia*, 385 F.3d at 965-66. The state-law tort causes of action asserted by respondents would not go forward but for respondents successfully proving a "fraud-on-the-FDA."

It does not matter to the analysis that the cause of action in *Buckman* was denominated fraud-on-the-FDA, while the cause of action in this case incorporates agency fraud as a prerequisite to traditional tort liability. Nothing in *Buckman* suggests that its holding should apply only when fraud-on-the-FDA is a "positive" element of a cause of action's required proof. Rather, the focus in *Buckman* was on the *practical effect* of the adjudication of the claim: whether it would involve the fact-finder in an area committed to federal regulation, thereby creating an inevitable conflict with the federal scheme. 531 U.S. at 348-51; see *id.* at 353 (federal inquiry was "a critical element of [plaintiff's] case"). The Second Circuit's fixation on what respondents here pleaded (violations of a state duty in addition to federal duty) imbues the procedural posture of *Buckman* with far more significance than is warranted in light of this Court's analysis in striking down the state-law claims. In any event, this distinction is moot because respondents actually plead fraud-on-the-FDA in their complaints. See Pet. App. 337a, 344a, 354a; JA 33, 36, 43.

Adopting the Second Circuit's formalistic approach would lead to absurd results. Under it, a State would be prohibited from amending a common law tort cause of action to incorporate fraud-on-the-FDA as a formal element of a claim (as the State did in *Buckman*). Inexplicably, however, a State would be

permitted to achieve the same result by amending the cause of action to incorporate fraud-on-the-FDA as a prerequisite to liability (as the State did here). See Pet. App. 19a-21a. This approach is squarely at odds with the functional approach of *Buckman*. It would, moreover, render preemption analysis nothing more than a semantic game, a system that state legislatures (and, to a large degree, plaintiffs) could gerrymander around simply by phrasing fraud-on-the-FDA as a condition precedent to liability, rather than a formal element of the claim. There is no basis to permit such an end-run around the analysis of *Buckman*.

The fundamental problem with the claims at issue in *Buckman* was not that the plaintiffs there failed to "rely[] on traditional state tort law which had predated the federal enactments" but that, "[o]n the contrary, the existence of these federal enactments [was] a critical element of their case." *Buckman*, 531 U.S. at 353. The same concern applies here. Respondents may bring traditional state tort causes of action, but those claims can proceed only if respondents can prove that the manufacturer failed to comply with federal statutory and regulatory requirements. Mich. Comp. Laws § 600.2946(5)(a); see Pet. App. 20a-21a. This is no different than *Buckman*. In both circumstances, the "federal enactments [are] a critical element," without which the plaintiffs' claims cannot go forward. *Buckman*, 531 U.S. at 353.

2. Second, the court below erred in purporting to distinguish *Buckman* on the basis that the cause of action at issue there was premised exclusively on fraud against FDA and had no non-federal elements. Pet. App. 20a. No such distinction exists. A showing of fraud-on-the-FDA was as necessary for plaintiffs to

prove their claims in *Buckman* as it is necessary for respondents to maintain their claims under Michigan law. In neither case, though, would proving such fraud alone be sufficient to trigger liability. Rather, the plaintiffs in *Buckman* also were required to prove, in addition to the violation of the federal duty itself, that the violation led to marketing a product that presented an unreasonable risk of injury, and that harm was caused to the plaintiffs as a result. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 826-29 (3d Cir. 1998) (discussing elements of fraud-on-the-FDA claim), *rev'd on other grounds sub nom. Buckman*, 531 U.S. 341; see also *Buckman*, 531 U.S. at 347 (noting claims required proof that products were used "to the plaintiffs' detriment"). These elements of proof mirror those necessary to impose liability on a defendant under the Michigan product liability scheme, *i.e.*, that, as a result of federal law violations, defendant was able to market a product with an unreasonable risk of harm, and that plaintiff was harmed as a consequence. See Mich. Comp. Laws § 600.2946(5)(a); *Gregory* v. *Cincinnati Inc.*, 538 N.W.2d 325, 329 (Mich. 1995); *Reeves* v. *Cincinnati, Inc.*, 439 N.W.2d 326, 329 (Mich. Ct. App. 1989).

The only possible divergence between the claims here and those in *Buckman* is that the latter provided for damages based directly upon the fraud itself, see 531 U.S. at 343, 347, while the former treats fraud as a condition precedent to recovery, independent of the damages calculation, see Mich. Comp. Laws § 600.2946(5)(a). But such a distinction, assuming it exists, is without difference. As discussed, both causes of action require that the fact-finder pass upon the manufacturer's compliance with FDA disclosure requirements. That this element forms part of the

causal chain of liability in one claim (*Buckman*) but stands as a condition precedent to liability in the other (here) does not alter the fact that both causes of action contemplate—indeed, demand—that the fact-finder infringe on an area dedicated exclusively to federal regulation. See *Garcia*, 385 F.3d at 966; see also 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349-51. *Buckman* is materially indistinguishable from, and therefore controls, this case. *Garcia*, 385 F.3d at 966.

3. Nothing in the Second Circuit's analysis alters why *Buckman* is controlling here. The claims in both cases share the same essential attribute: they demand proof of fraud-on-the-agency as a pre-requisite to a finding of liability. 531 U.S. at 349-53; see also *Garcia*, 385 F.3d at 965-66 (concluding that any distinctions between the Michigan regime and the cause of action at issue in *Buckman* were "immaterial in light of *Buckman*" because "'*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims'") (quoting district court). Here, as in *Buckman*, the Michigan exception requires a lay jury to pass on the manufacturer's noncompliance with FDA disclosure requirements, encroaching upon a field of exclusive federal control, and inevitably conflicting with federal statutory and regulatory provisions. *Buckman*, 531 U.S. at 349-53. Rather than governing the relationship between pharmaceutical companies and Michigan citizens, the provision here and the claims in *Buckman* impermissibly seek to regulate the relationship between pharmaceutical companies *and the FDA*.

The federal-law inquiry put to the trier-of-fact under the Michigan exception impermissibly allows juror "speculation about what [a federal agency] might have done had it been faced with the facts of

this case." *Arkansas La. Gas Co.* v. *Hall*, 453 U.S. 571, 578-79 (1981). This is not an area in which "coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes." *New York State Dep't of Soc. Servs.* v. *Dublino*, 413 U.S. 405, 421 (1973).[16] Thus, applying the rule in *Buckman* here would not, as the Second Circuit suggested, "gut[]" state tort law or otherwise modify the "traditional state law duties between pharmaceutical companies and their consumers." Pet. App. 20a. It simply limits state law from permitting fact-finders to invade the exclusively federal province at issue here.

C. *Buckman* Did Not Hinge On Fraud-On-The-Agency Being A Cause Of Action, Rather Than A Showing Required To Rebut An Affirmative Defense.

In a variation of the theme just discussed, the Second Circuit also deemed *Buckman* distinguishable because, under Michigan's provision, fraud-on-the-agency "is not even an *element* of a products liability claim." Pet. App. 23a. The court of appeals found it significant that the statute "does no more than create a defense that drug makers may invoke, if they so decide, and that it is not up to the plaintiff to prove fraud as an element of his or her claim." *Id.* at 24a.

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[16] Contrary to the Second Circuit's suggestion, *Lohr* does not change this analysis. *See* Pet. App. 21a-22a. The claims in *Lohr* neither arose from nor depended on federal law, whereas the claims in this case "survive[] only [if] there [is] evidence of fraud against the FDA." *Id.* 22a. Accordingly, as the *Buckman* Court explained, *Lohr* has no bearing on the preemption analysis in this case. *See* 531 U.S. at 352 (concluding that *Lohr* is an express preemption case that "did not squarely address the question of implied pre-emption" at issue in a fraud-on-the-agency inquiry).

1. The Second Circuit failed to articulate how these facial differences are relevant, in any way, to this Court's analysis in *Buckman*. And they are not. As shown, the driving considerations in *Buckman* were that (1) proof of fraud-on-the-agency (and the accompanying remedy) requires an impermissible intrusion into a field strictly within the purview of the agency alleged to have been defrauded, and (2) allowing lay jurors to make these findings imposes a direct conflict with and an obstacle to FDA's determinations within a carefully calibrated federal regulatory scheme. See 531 U.S. at 347-50.

These considerations do not depend on whether proof of fraud-on-the-agency is required in the first instance or only after an affirmative defense has been raised. In both circumstances, fact-finders improperly are empowered "to punish and deter fraud against the [FDA]" in spite of what FDA itself has done and the "delicate balance of statutory objectives" the agency has sought to fulfill. *Id.* at 348.[17]

2. The folly of the Second Circuit's focus on causes of action versus elements required to defeat an affirmative defense, while downplaying the federal inquiry required to prove each, is further highlighted by considering the analysis in this Court's complete preemption cases. Although a federal question inquiry is not at issue here, the complete preemption

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[17] *See also, e.g., In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, MDL-1699, 2006 WL 2374742, at *10 (N.D. Cal. Aug. 16, 2006) ("a claim premised on a drug manufacturer's failure to provide data to the FDA is preempted"); Pet. App. 328a-329a (*Ledbetter v. Merck & Co.*, No. 2005-58543 (Tex. Dist. Ct. Apr. 20, 2007) ("Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same" and "permitting a [State] jury or judge to make the [*Buckman*] inquiry would impinge on a uniquely federal issue")).

doctrine provides a useful point of comparison. It makes plain that where federal issues are substantial and intertwined with state law, it is immaterial whether they are part of the cause of action or their resolution is simply necessary to the case's ultimate resolution. See, *e.g.*, *Smith* v. *Kansas City Title & Trust Co.*, 255 U.S. 180, 199 (1921) (discussing "right to relief depend[ing] upon the construction or application of the Constitution or laws of the United States").

Extrapolating from this Court's complete preemption principles, irrespective of whether the fraud-on-the-FDA inquiry is taken as an element of a state claim or a showing required of a plaintiff to overcome an affirmative defense, the federal issues here are so closely interwoven with the state claims that the resolution of the latter necessarily depends on determination of the former. No matter how postured, assessing whether a defendant violated a duty created by *federal* statute or regulation and owed to a *federal* agency and, if so, what action the *federal* agency with exclusive enforcement power should take are "subjects within the purview of the constitution" akin to those which trigger "the importance, and even necessity of *uniformity* of decisions throughout the whole United States." *Martin* v. *Hunter's Lessee*, 14 U.S. (1 Wheat.) 304, 347-48 (1816); cf. *Michigan* v. *Long*, 463 U.S. 1032, 1038-40 & n.4 (1983).

Given that the Michigan provision attempts to "place[] the federal law into a context where it will operate to shape behavior," and there is a strong "possibility that the federal law will be incorrectly interpreted in the context of adjudicating the state-law claim," *Thompson*, 478 U.S. at 828 (Brennan, J., dissenting), the same implied preemption concerns

that animated the Court's decision in *Buckman* are determinative here.

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Because the Michigan provision requires the trier-of-fact to make the very same inherently federal determination held to be impermissible in *Buckman*, it is preempted by federal law.[18]

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[18] The Sixth Circuit, which includes the State of Michigan, already has determined that Michigan severability law would let stand the remainder of Mich. Comp. Laws § 600.2946(5). *See Garcia*, 385 F.3d at 966-67; *see also Duronio* v. *Merck & Co.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006) (per curiam) (following *Garcia* in unpublished disposition). There is no reason for this Court or the Second Circuit below to reconsider this issue of Michigan state law. *See, e.g., Elk Grove Unified Sch. Dist.* v. *Newdow*, 542 U.S. 1, 16 (2004) ("Our custom on questions of state law ordinarily is to defer to the interpretation of the Court of Appeals for the Circuit where the State is located."); *MacGregor* v. *State Mut. Life Assur. Co.*, 315 U.S. 280, 281 (1942) (per curiam) (absent State authority, "we shall leave undisturbed the interpretation placed on purely local law by a Michigan federal judge . . . and by three circuit judges whose circuit includes Michigan."); Pet. App. 11a (Second Circuit "defer[s] conclusively to another circuit's judgment only when that court of appeals' decision addressed questions of *state* law from a state within that circuit").

CONCLUSION

For these reasons, the Second Circuit's decision should be reversed and the judgment of the district court should be restored.

Respectfully submitted,

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APPENDIX

APPENDIX A

STATUTES

21 U.S.C. § 336. Report of minor violations

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

21 U.S.C. § 375. Publicity

* * * * *

(b) Information regarding certain goods

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

APPENDIX B

REGULATIONS

21 C.F.R. § 20.1 Testimony by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.

(b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: *Provided*, That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is

determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

21 C.F.R. § 314.125 Refusal to approve an application.

(a) The Food and Drug Administration will refuse to approve the application and for a new drug give the applicant written notice of an opportunity for a hearing under § 314.200 on the question of whether there are grounds for denying approval of the application under section 505(d) of the act, if:

(1) FDA sends the applicant an approvable or a not approvable letter under § 314.110 or § 314.120;

(2) The applicant requests an opportunity for hearing for a new drug on the question of whether the application is approvable; and

(3) FDA finds that any of the reasons given in paragraph (b) of this section apply.

(b) FDA may refuse to approve an application for any of the following reasons:

(1) The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product are inadequate to preserve its

identity, strength, quality, purity, stability, and bioavailability.

(2) The investigations required under section 505(b) of the act do not include adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(3) The results of the tests show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling or the results do not show that the drug product is safe for use under those conditions.

(4) There is insufficient information about the drug to determine whether the product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(5) There is a lack of substantial evidence consisting of adequate and well-controlled investigations, as defined in § 314.126, that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling.

(6) The proposed labeling is false or misleading in any particular.

(7) The application contains an untrue statement of a material fact.

(8) The drug product's proposed labeling does not comply with the requirements for labels and labeling in Part 201.

(9) The application does not contain bioavailability or bioequivalence data required under

part 320 of this chapter.

(10) A reason given in a letter refusing to file the application under § 314.101(d), if the deficiency is not corrected.

(11) The drug will be manufactured or processed in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the act and Part 207.

(12) The applicant does not permit a properly authorized officer or employee of the Department of Health and Human Services an adequate opportunity to inspect the facilities, controls, and any records relevant to the application.

(13) The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product do not comply with the current good manufacturing practice regulations in Parts 210 and 211.

(14) The application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.

(15) A nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no

reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(16) Any clinical investigation involving human subjects described in the application, subject to the institutional review board regulations in part 58 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(17) The applicant or contract research organization that conducted a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter that is contained in the application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(18) For a new drug, the application failed to contain the patent information required by section 505(b)(1) of the act.

(c) For drugs intended to treat life-threatening or severely-debilitating illnesses that are developed in accordance with §§ 312.80 through 312.88 of this chapter, the criteria contained in paragraphs (b) (3), (4), and (5) of this section shall be applied according to the considerations contained in § 312.84 of this chapter.

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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

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QUESTION PRESENTED

A Michigan statute provides that a drug manufacturer is not liable to a patient injured by a drug if the FDA ("Food and Drug Administration") approved the drug for marketing and the drug and its labeling complied with the FDA's approval. The statute further provides that this defense does not apply if the defendant has intentionally withheld information from or misrepresented information to the FDA that was required to be submitted, and the FDA would not have approved the drug or would have withdrawn approval if the information had been accurately submitted. The question presented is

Whether federal regulation of drugs impliedly preempts application of the exception to the defense provided under the Michigan statute, while leaving the defense itself intact.

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INTRODUCTION

Traditional state tort law allows a manufacturer, alleged to have sold a defective product, to use compliance with federal standards or regulations as evidence that the product was not defective or that the manufacturer acted non-negligently. In most states, such evidence is not controlling. However, in 1995, Michigan enacted a statute providing that, with respect to drug manufacturers, federal approval and compliance with Food and Drug Administration ("FDA") approval requirements generally precludes liability for injuries caused by their products. The Michigan legislature chose not to extend this defense to situations in which it lacked confidence that the federal approval could be relied on as dispositive evidence that the manufacturer satisfied state-law duties of care. Accordingly, the statute also provides that, if a drug manufacturer did not comply with FDA disclosure requirements and the non-compliance affected the FDA's approval decision, the statutory defense does not apply.

Petitioner Warner-Lambert Company argues that the non-compliance exception to Michigan's statutory defense is preempted because it is premised on three showings or findings, each of which the company claims conflicts with the FDA's authority. Specifically, Warner-Lambert argues that the state law is preempted because it calls for consideration of what information the manufacturer was required to disclose and report, whether the company complied with those federal requirements, and whether the FDA would have refused to approve or withdrawn approval of the drug if the company had not misrepresented or omitted relevant information. The first two showings, however, are no different from those offered by *manufacturers* themselves in product liability cases involving injuries

caused by drugs, automobiles, and other regulated products. These two topics are also litigated in negligence per se cases, about which the Court in other federal preemption cases has expressed approval, not concern. The broad range of claims and defenses that have for decades involved the first two showings challenged by Warner-Lambert—and the notable lack of evidence that such claims and defenses have caused any impediment to the functioning of the federal regulatory scheme—belies Warner-Lambert's preemption argument as to these showings.

As for the finding of how the FDA would have reacted to a complete and honest disclosure, Warner-Lambert's argument turns on its misunderstanding that Michigan law is seeking to police compliance with FDA regulations. In fact, the statute seeks only to withhold a state-law defense from companies whose actions have negated the premise of the defense—that is, that regulatory approval provides a sound basis for concluding that a drug is not defective. Thus, contrary to Warner-Lambert's suggestion, a finding that the FDA would have withdrawn approval had the company made accurate disclosures is not equivalent to a finding that the company should be punished for lying to the agency. Rather, the finding only allows the case to pass the hurdle erected by the Michigan statute, so that the case may be litigated as a traditional common-law claim. Because the statute does not impose liability for "fraud on the FDA," Warner-Lambert's preemption arguments should be rejected.

STATEMENT OF THE CASE

The Regulatory Scheme

Under the Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer seeking to market a new prescription

drug must first file a new drug application ("NDA") with the FDA. 21 U.S.C. § 355(a). The NDA must include, among other things, full reports of investigations conducted to determine the safety and effectiveness of the drug, a full description of manufacturing methods and controls for the drug, and samples of the proposed labeling to be used for the drug. *Id.* § 355(b)(1). The agency will approve the NDA unless it finds specified grounds for denying it, including that test results and other information fail to establish that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," that there is a lack of "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," or that, "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." *Id.* § 355(d).

Because prescription drug labeling provides information used by clinicians to prescribe and administer an approved drug, the FDA's regulations describe in detail the proper form and content for labeling. *See generally* 21 C.F.R. Part 201. Once the agency approves a drug for marketing, the drug generally must be accompanied by labeling in the form approved by the FDA. *See* 21 C.F.R. § 314.70(b)(2)(v). However, a manufacturer must revise its labeling "to include a warning as soon as there is reasonable evidence of an association of a serious hazard" with the drug. *Id.* § 201.80(e). Some labeling changes require FDA pre-approval, but manufacturers are permitted to make revisions, without prior FDA approval, to

> add or strengthen a contraindication, warning, precaution, or adverse reaction; [and to] add or

> strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product[.]

Id. § 314.70(c)(6)(iii)(A), (C); *see also* 44 Fed. Reg. 37434, 37447 (1979) (revised warnings may be communicated by various means, including label changes and "Dear Doctor" letters).

"Many serious ADRs [adverse drug reactions] are discovered only after a drug has been on the market for years." Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (May 1, 2002). To monitor these adverse reactions, the FDA requires companies to submit an "adverse event report" within 15 days of a "serious and unexpected" experience. 21 C.F.R. § 314.80(c)(1). All other adverse drug experiences must be reported quarterly for three years after approval of an NDA and annually after three years have passed. *Id.* § 314.80(c)(2).

Factual Background

In July 1996, Warner-Lambert, through its Parke-Davis division, submitted to the FDA an NDA for a diabetes drug called troglitazone, to be marketed under the brand name Rezulin. Rezulin is in a category of drugs called glitazones. No other drug in that category had ever been approved by the FDA.

Even before Warner-Lambert submitted the NDA, it knew that the FDA was concerned about an association between Rezulin and liver toxicity. While aware as early as 1993 of Rezulin's potential harm to the liver, *see* Wilman, *Risk Was Known as FDA Okd Fatal Drug*, L.A. Times, Mar. 11, 2001, Warner-Lambert chose to omit

from its FDA submissions information that showed this concern to be valid.[1]

For example, at the FDA advisory committee meeting held in December 1996 to consider the Rezulin NDA, Randall Whitcomb, Warner-Lambert's vice president for diabetes research, stated that the occurrence of liver injury among Rezulin patients was "comparable to placebo." FDA, Transcript of Endocrinologic and Metabolic Advisory Committee Meeting, Dec. 11, 1996, at 152, *available at* http://www.fda.gov/ohrms/dockets/ac/96/transcpt/3255t2b.pdf; *see id.* at 147. In fact, the incidence of liver injury among patients who took Rezulin was more than three times higher than the incidence among patients who took a placebo. *See* Whitcomb & Watkins, *Hepatic Dysfunction Associated with Troglitazone*, 338 New Eng. J. Med. 916 (1998) (letter from Warner-Lambert acknowledging that clinical trial data showed Rezulin's association with liver injury); *Risk Was Known as FDA Okd Fatal Drug*, *supra* (quoting Whitcomb's deposition testimony in other cases). And although the company reported only one case of jaundice to the FDA Advisory Committee, it knew that at least four patients had suffered jaundice, and 12 had experienced potentially life-threatening liver toxicity. *Id.*; *see* Whitcomb & Watkins, *supra*, at 916. A physician who conducted early research on Rezulin

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[1]The facts in the underlying cases were not developed below because the cases were dismissed on motions for judgment on the pleadings under Federal Rule of Civil Procedure 12(c), prior to litigation on the merits. The facts stated here—based on allegations in the complaints, publicly available sources, and two documents produced to lawyers in the multidistrict litigation of which respondents' cases are a part and filed as exhibits in other Rezulin cases—reflect what respondents will attempt to prove if the case proceeds.

later wrote that Warner-Lambert "deliberately omitted reports of liver toxicity and misrepresented serious adverse events experienced by [Rezulin] patients in their clinical studies." *Risk Was Known as FDA Okd Fatal Drug*, *supra* (quoting letter sent from company consultant to Senator Edward Kennedy).

In January 1997, the FDA approved Rezulin for use in combination with insulin or other diabetes drugs. JA 31. In May 1997, Warner-Lambert submitted a safety update indicating that, in liver function tests, no Rezulin patients showed liver enzymes in excess of three times the upper limit of normal.[2] JA 33. In August, approval was expanded to allow use of Rezulin as a stand-alone diabetes therapy. JA 32. The approval letter reiterated the reporting requirements imposed on manufacturers of approved drugs. *See* Letter from FDA to Parke-Davis Pharmaceutical Research, Aug. 4, 1997, *available at* http://www.fda.gov/cder/foi/nda/97/020720_s02_s03_s05ap.pdf. In October, an FDA medical officer complained to Warner-Lambert that, based on his review of clinical trial results, critical data about Rezulin's potential for liver toxicity had been omitted from the May report. JA 34. The company later admitted that 20 study participants had experienced liver enzyme elevations higher than it had reported to the FDA, including five whose elevated enzymes were significantly higher. *See* Whitcomb & Watkins, *supra*.

Although reports of serious adverse events started to flow in to the FDA, some FDA medical staff continued to support Rezulin. Rather than withdrawing approval, the FDA negotiated a series of labeling changes with Warner-Lambert, eventually resulting in five changes in

---

[2]An elevated level of liver enzymes in the blood is an indication of liver damage.

the three years that the drug was on the U.S. market.[3] The first labeling change described the incidence of adverse effects on the liver as "rare." *See* Letter from Parke-Davis to Healthcare Professional, Oct. 28, 1997, *available at* http://www.fda.gov/medwatch/safety/1997/rezuli.htm (quoting labeling change). Each subsequent change recommended increasingly frequent liver monitoring.

On December 1, 1997, Glaxo Wellcome, which sold the drug in Britain, withdrew it from the market there because "the pace of liver injuries and deaths was by that point 'unacceptably high.'" JA 34-35. A few days later, as evidenced in an email produced in litigation (#QMET-022-0968), an FDA medical officer told Warner-Lambert that if the agency had known the true safety data when it was considering whether to approve Rezulin as a solo therapy, it would not have approved that use. That same month, the FDA requested that Warner-Lambert stop marketing Rezulin as a stand-alone therapy. *See* Wilman, *"Fast-Track" Drug to Treat Diabetes Tied to 33 Deaths*, L.A. Times, Dec. 7, 1998. Warner-Lambert resisted and did not do so until June 1999. *See* Letter from Parke-Davis to Healthcare Professional, June 17, 1999, *available at* http://www.fda.gov/medwatch/safety/1999/rezuhp.htm.

Warner-Lambert tried to conceal the extent of the danger posed by Rezulin not only from the FDA, but from physicians as well. For example, in February 2000, Warner-Lambert released a statement claiming that it believed that no liver-failure deaths were attributable to

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[3]At that time, the FDA did not have authority to dictate labeling changes. The statute has since been amended to augment the FDA's authority in this regard. *See* Pub. L. No. 110-85, 121 Stat. 823, § 901 (Sept. 27, 2007), *to be codified at* 21 U.S.C. § 355(o)(4).

Rezulin after the June 1999 label change. *See* Warner-Lambert, *Warner-Lambert responds to recent Rezulin media reports* (Feb. 24, 2000), *available at* http://web.archive.org/web/20001204094600/www.warnerlambert.com/press/release.asp?release=106. The FDA discredited that statement the next day, pointing to six instances of liver failure that post-dated June 1999, three of which resulted in the patients' deaths. Wilman, *Update*, L.A. Times, Feb. 29, 2000 (quoting FDA spokesperson).

In March 2000, Warner-Lambert stopped selling Rezulin in the United States altogether. HHS News, *Rezulin to be Withdrawn from the Market* (Mar. 21, 2000), *available at* http://www.fda.gov/bbs/topics/NEWS/NEW00721.html.

When the FDA was considering the Rezulin NDA and during the period when the drug was on the market, the FDA was aware that Rezulin presented potential risks. However, as one FDA medical officer noted in an email produced in the MDL (#REZ1006968), "one would have had to be 'clairvoyant' to predict the risk of liver failure from the NDA data, given the manner in which [the company] represented those data."

Respondents include 13 patients who suffered serious liver damage as a result of taking Rezulin, the estates of 6 patients who died from liver damage, and the spouses of 8 of these 19 patients. All respondents are Michigan residents.

The Michigan Statute

Respondents are plaintiffs in four separate suits, all brought in the Eastern District of Michigan but transferred to a multidistrict litigation in the Southern District of New York. *See* 28 U.S.C. § 1407. Throughout

litigation of the MDL and other Rezulin lawsuits, Warner-Lambert's defense has relied heavily on the FDA's approval of Rezulin, the company's interactions with the FDA, and its submissions to the FDA. For the MDL plaintiffs from Michigan, this defense poses a particular challenge.

Before 1995, Michigan allowed defendant-manufacturers in product liability cases to present evidence of compliance with government standards. Such compliance was admissible but not conclusive evidence that the defendant had acted non-negligently or that its product was not defective. *Owens-Allis Chalmers Corp.*, 325 N.W.2d 372, 375-76 (1982) (discussing then-current version of Mich. Comp. Laws § 600.2946). That approach is still followed in the vast majority of states. *See Restatement (Third) of Torts: Prods. Liab.* § 4 Reporters' Note, cmt. e (1998) ("*Restatement (Third)*").

In 1995, Michigan amended its product liability law to address drug manufacturers' liability in particular. The law now provides that evidence of FDA approval and compliance with the terms of the approval bars a claim for negligence or product defect, unless the drug was sold after the FDA withdrew approval. Mich. Comp. Laws § 600.2946(5); *see Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003) (statute provides "absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval"). The Michigan statute contains two exceptions:

> This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration

> information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Mich. Comp. Laws § 600.2946(5) (citations omitted).

In providing a compliance-based defense, this statute is little different from the product liability law in most states, where a defendant may use compliance with federal law as evidence that a product was not defective. *Restatement (Third)* § 4 & Reporters' Note cmt. e. However, unlike in most jurisdictions, in Michigan that evidence is dispositive in a case against a drug manufacturer, unless the plaintiff can show either bribery or that the company did not disclose required information to the FDA and that, had it done so, the agency would not have approved or would have withdrawn approval of the product.

Proceedings Below

In the multidistrict litigation below, Warner-Lambert raised the defense set forth in the Michigan statute and moved to dismiss the Michigan cases on the ground that the paragraph (a) rebuttal to the statutory defense was impliedly preempted under the reasoning of *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and was severable from the rest of the statute. The district court agreed with Warner-Lambert and dismissed the Michigan cases. Pet. App. 38a.

On appeal, the Second Circuit reversed, finding that *Buckman* did not control the case and that the exception to the Michigan defense was not impliedly preempted. In *Buckman*, this Court considered whether the Medical Device Amendments to the FDCA impliedly preempt a state-law claim for "fraud on the FDA." There, plaintiffs injured by bone screws had alleged that the defendant had misrepresented the intended use of the screws to the FDA and that, had the defendant disclosed the actual intended use, the FDA would not have granted permission to market the product. The plaintiffs had contended that the fraud on the agency caused their injury and was itself actionable under state tort law. 531 U.S. at 343.

In this case, the Second Circuit first explained that the analysis here differs from that in *Buckman*. In *Buckman*, the presumption against preemption did not apply to a claim premised entirely on fraud on the agency because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." Pet. App. 16a (citing 531 U.S. at 347). In contrast, the Second Circuit noted, the Michigan statute does not create a new cause of action for fraud on the agency but rather places a condition on victims' ability to recover under preexisting state tort law—the very type of traditional state law at the heart of the presumption against preemption.

Turning to the merits of the preemption issue, the court of appeals found three meaningful differences between a rebuttal to a defense to claims under traditional state tort law and the fraud-on-the-FDA claim at issue in *Buckman*. First, the "source and 'vintage'" of the duty that the defendant is accused of breaching in tort cases such as this one are different from the source and vintage of the duty at issue in *Buckman*. Pet. App.

20a (quoting *Buckman*, 531 U.S. at 352). Here, the state-law duties on which the plaintiffs premise their claims are all duties traditionally recognized by the common law; none is a "newly-concocted duty between a manufacturer and a federal agency." *Id.*

Second, in a fraud-on-the-FDA claim, proof of fraud is alone sufficient to impose liability because there are "no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements." *Id.* 20a-21a. Thus, in *Buckman*, the fraud claims existed solely by virtue of the FDA disclosure requirements. In fact, on that basis, *Buckman* had expressly distinguished *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which the Court held that state product liability claims against a medical device manufacturer were not preempted, including claims premised on common-law duties that paralleled federal duties. Pet. App. 21a (citing *Buckman*, 531 U.S. at 352-53). Similarly, the Second Circuit reasoned, the complaints in this case allege "violations of common-law duties long-recognized by Michigan's tort regime." *Id.* "The pre-existing claims survive M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike in *Buckman*, they are anything but solely based on the wrong of defrauding the FDA." *Id.*

Third, the Second Circuit observed that proof of fraud is not an element of a tort claim in Michigan and becomes relevant only if the drug manufacturer-defendant asserts FDA approval as a defense. Pet. App. 23a (citing *Taylor*, 658 N.W.2d at 131). Indeed, it is the defendant that first raises the issue of the FDA's findings and actions, in contrast to a fraud-on-the-agency claim, where the plaintiff injects the administrative proceedings into the litigation.

Finally, the Second Circuit cautioned against the breadth of Warner-Lambert's preemption argument. "Finding preemption of traditional common law claims where proof of fraud is not even a required element—but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law—would result in preemption of a scope that would go far beyond anything that has been applied in the past." Pet. App. 24a. Without explicit direction from Congress, the court was unwilling to invalidate "state common law claims merely because issues of fraud may arise in the trial of such claims." *Id.*

SUMMARY OF ARGUMENT

I. This case involves the scope of a state-law defense to traditional tort claims. The Michigan statute that establishes the defense and the showing needed to rebut it are elements of Michigan's tort system, which is not aimed at policing conduct before the FDA, but at redressing violations of duties of care owed by manufacturers to consumers. As *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), *Medtronic v. Lohr*, and other of this Court's cases make clear, where the state is exercising its historic authority to protect the health and safety of its citizens, a presumption against preemption applies.

II. In *Buckman*, this Court held that a state-law "fraud-on-the-FDA" claim conflicts with FDA regulation and, therefore, is impliedly preempted by federal law. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." 531 U.S. at 348. That balance, the Court explained, "can be

skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* Here, respondents have not alleged a "fraud-on-the-FDA" claim. Rather, they seek to pursue only traditional damages claims based on tort theories that predate the federal drug laws. Such claims do not trigger the concerns at issue in *Buckman*. *See id.* at 352 (distinguishing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), on the ground that the claim in that case was based on traditional state tort law).

Relying primarily on *Buckman*, Warner-Lambert argues that the exception to § 600.2946(5) for instances in which a drug manufacturer has misled the FDA or failed to make required disclosures is subject to either field or conflict preemption. The company contends that consideration of evidence about what a manufacturer was required to disclose to the FDA, evidence showing whether a manufacturer complied with those requirements, and evidence about how the FDA would have reacted to honest and complete submissions each intrude on or pose an obstacle to the exercise of the FDA's authority. The first two showings, however, are unremarkable elements of a range of litigation—from negligence per se cases against regulated companies, to criminal cases against such companies. Moreover, the two showings are standard elements of the regulatory compliance defense available to manufacturers in product liability cases in all 50 states. The regularity with which these showings are made in state-law tort litigation—including by Warner-Lambert—belies the preemption claim.

As for the finding about how the FDA would have reacted if the company had made honest submissions, Warner-Lambert's preemption argument turns on the misunderstanding that Michigan is attempting to police compliance with FDA regulations. The Michigan

statute, however, is not an effort to enforce FDA regulations. Rather, the paragraph (a) deceit exception, like the paragraph (b) bribery exception, represents a decision to withhold a statutory defense where the premise of the defense—that FDA approval represents a fair and expert finding of safety and effectiveness—does not apply. Put differently, § 600.2946(5) reflects Michigan's judgment that a drug is not defective, as a matter of law, if it has FDA marketing approval, but that if circumstances, such as misrepresentation or bribery, eliminate the state's confidence that the approval can be relied on as dispositive evidence that the manufacturer satisfied state-law duties of care, then the state will not conclusively deem the product to be non-defective or the manufacturer's conduct to be non-negligent.

Warner-Lambert also relies on purported burdens imposed by the Michigan law. Yet the overwhelming majority of jurisdictions have long allowed manufacturers to show compliance with federal regulations as evidence of non-defect or non-negligence and allowed plaintiffs to rebut that evidence. This traditional framework would seem to raise the same risk of obstacles and burdens as Warner-Lambert describes with respect to the Michigan statute, but no obstacles or burdens have materialized.

III. If the Court holds that some or all of the paragraph (a) exception to § 600.2946(5) is preempted, the case must be remanded to allow the court below to consider whether the preempted portion is severable from the rest of the statute. This issue, which was briefed and argued below, presents a question under Michigan state law. Warner-Lambert did not include it in the question presented, but suggests in its brief that the Court reach out to decide it by deferring to the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labora-*

tories, 385 F.3d 961 (6th Cir. 2004), which held that paragraph (a) of § 600.2946(5) was preempted in most instances and was severable from the rest of subsection (5). However, whether this Court or the Second Circuit should defer to the Sixth Circuit's decision on this issue is not before the Court and is properly left to the Second Circuit on remand.

ARGUMENT

I. A PRESUMPTION AGAINST PREEMPTION APPLIES HERE.

This Court's decisions have repeatedly emphasized that "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In considering whether the first exception to Michigan's FDA-approval defense is impliedly preempted by federal law, the Second Circuit properly took as its starting point that "the presumption against federal preemption of state law obtains in the case before us." Pet. App. 18a.

A. Relying on *Buckman*, Warner-Lambert and its amici contend that the presumption does not apply here because, they say, the state has strayed beyond its traditional police-power role of creating remedies for people injured by unsafe products. They claim that the state has instead attempted to interfere with "the relationship between a federal agency and the entity it regulates," *Buckman*, 531 U.S. at 347, and hence, that no presumption against preemption applies.

As the Second Circuit recognized, Warner-Lambert's argument ignores fundamental differences between the claim in *Buckman* and the conditional defense made available by the Michigan law. The claim in *Buckman* was premised on the alleged violation of a duty owed to the FDA, not to the plaintiff. As this Court explained, the essence of the claim was that the manufacturer had "made fraudulent representations to the [FDA] in the course of obtaining approval to market" its products, *id.* at 343, and the Court thus aptly and repeatedly described the purported cause of action as a "'fraud-on-the-FDA claim." *Id.* at 347, 348, 350, 351. Such claims, the Court held, are not entitled to a presumption against preemption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* at 347 (quoting *Rice*, 331 U.S. at 230); *see also id.* at 353 (plaintiffs not "relying on traditional state tort law which had predated the federal enactments"). At the same time, *Buckman* expressly distinguished cases, such as *Silkwood*, 464 U.S. 238, in which issues of federal regulatory compliance arise in the context of state-law personal injury actions based on "traditional state tort law principles of the duty of care owed by" the defendant to the plaintiff. *Buckman*, 531 U.S. at 352; *see also id.* (distinguishing *Medtronic*, 518 U.S. at 481, in which the "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements").

Here, unlike in *Buckman*—but as in *Silkwood* and *Medtronic*—the state law at issue is not an attempt to "police" conduct before the federal agency. Rather, the law is part of a traditional state tort system aimed at redressing violations of duties of care owed by drug manufacturers to the individuals who use their

products. The underlying basis of the claim against Warner-Lambert is its breach of the common-law duty of care. The challenged statute creates a defense (compliance with federal licensing requirements) to what might otherwise be a breach of that duty of care (marketing an unsafe product), and then limits that defense so that it is not improvidently extended to a defendant that did not in fact comply with the federal requirements. In other words, the law in question is neither aimed at regulating the conduct of manufacturers before the agency, nor premised on an underlying duty to comply with federal law. Rather, the Michigan law circumscribes the availability of a defense to an action aimed at enforcing state common-law duties devised to protect the health and safety of the public.

As Warner-Lambert points out, the preemption argument here does not directly target the underlying tort claim, but rather the bounds of the state-law defense. However, as reflected by the *Restatement (Third)* § 4(b) and comment e, regulatory compliance defenses, and their limitation to cases in which the regulatory process is not "tainted" by the defendant's fraud, misconduct, or violation of regulatory requirements, are a traditional component of state tort-law systems. The existence of such defenses (and of conditions or limitations on them) does not transform the state's law into an improper effort to interfere with the federal regulatory regime any more than would state tort-law duties that parallel federal regulatory requirements, such as those that the Court unanimously approved in *Medtronic*, 518 U.S. at 495; *id.* at 513, and *Bates*, 544 U.S. at 447. Because the purpose and function of the state law, as in *Silkwood*, *Medtronic*, and *Bates*, is not to enforce duties owed to federal agencies, but rather to determine the availability of a remedy for common-law duties

owed by the defendant directly to the plaintiff, the presumption against preemption should apply here, as it did in those cases.

To be sure, application of the presumption against preemption does not turn on the subjective motivation of state lawmakers. *See* Pet. Br. 39. But viewed objectively, the "function," "operation," and "effect," *id.*, of the Michigan law are entirely different from those of the purported "fraud-on-the-FDA" claim in *Buckman*. Unlike that claim, the function of which was to enforce duties derived entirely from the federal-law regulator-industry relationship, the law here functions solely to limit liability for a breach of a traditional state-law tort duty. There is no basis for displacing the well-established presumption against federal preemption of such laws.

B. This Court has repeatedly applied the presumption against preemption to claims of implied conflict preemption, as well as implied field preemption and express preemption.[4]

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[4]*See, e.g., Pharm. Research & Mfrs. Ass'n v. Walsh*, 538 U.S. 644, 661-62 (2003) (plurality opinion of Stevens, J., joined by Souter, Ginsburg & Breyer, JJ.) (in implied preemption case, starting with "presumption that the state statute is valid"); *id.* 680 n.4 (opinion of Thomas, J., concurring) (agreeing that presumption applied to implied preemption claim); *Johnson v. Fankell*, 520 U.S. 911, 918 (1997) (applying "our normal presumption against preemption" to claim that state statute barring interlocutory appeals impliedly conflicted with policies of 42 U.S.C. § 1983); *English v. General Elec. Co.*, 496 U.S. 72, 90 (1990) ("The 'teaching of this Court's decisions . . . enjoin[s] seeking out conflicts between state and federal regulation where none clearly exists.' *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960)."); *see also Medtronic*, 518 U.S. at 485 ("In all pre-emption cases, . . . we 'start with the assumption that the historic police powers of the States were

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Nonetheless, amicus curiae Chamber of Commerce, but not Warner-Lambert or the United States, argues that the presumption against preemption should not apply in implied conflict preemption cases. The Chamber cites no authority rejecting application of the presumption in such cases. It relies principally on decisions that simply did not repeat that the presumption applied when they turned to address the issue of implied conflict preemption. *See* Chamber Br. 10 n.7.[5]

Moreover, the type of conflict preemption alleged here—where the defendant claims that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), but does not claim that it is impossible to comply with both state and federal law—is very similar to field preemption in that it calls for a relatively open-ended assessment of the relationship of state law to allegedly

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[4](...continued)
not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'"). Five members of the Court in *Gade v. Nat'l Solid Wastes Mgmt. Ass'n* , 505 U.S. 88 (1992) similarly made clear that the presumption applies to implied conflict preemption cases. *See id.* at 110 (Kennedy, J., concurring); *id.* at 115-16 (Souter, J., dissenting).

[5]The Chamber cites *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), in which the opinion of the Court did not discuss the presumption, apparently because it was overcome by a clear conflict between state law and federal policy. The Chamber (at 12) wrongly suggests that *Geier* stands for the proposition that the presumption has "no relevance to a conflict preemption analysis." However, the portion of the opinion on which the Chamber relies is not discussing the presumption, but rather the argument that, because the Motor Vehicle Safety Act contains a savings clause, a "special burden" should be imposed on automakers claiming preemption in tort claims. *Geier*, 529 U.S. at 872-74 (rejecting argument made by dissent at 898).

overriding federal policies that are implicit in what Congress has done. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000); *see also, e.g., Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 615-16 (1991) (holding that reasons for rejecting field preemption claim also dictate rejection of claim of implied conflict with objectives of federal legislation); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65-70 (2002) (weighing similar policy considerations in assessing conflict and field preemption). In fact, Warner-Lambert concedes that it makes little or no difference whether its argument is labeled one of "narrow" field preemption or conflict preemption. Pet. Br. 21-22. Therefore, just as in implied field preemption cases, the Court should be reluctant to infer a preemptive federal policy in cases involving claims of "obstacle" preemption in the absence of either express preemptive language or the impossibility of compliance with both state and federal law.

II. FDA REGULATION DOES NOT PREEMPT § 600.2946(5)(a).

A. *Buckman* Does Not Control The Outcome Here.

In *Buckman*, the plaintiffs' theory was that, without the fraudulent representation of the manufacturer's consultant Buckman, the FDA would not have cleared the device for marketing, the manufacturer therefore would not have had access to the market to promote its device for an unapproved use, and the plaintiffs then would not have suffered injury from the unapproved use of the device. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 827 (3d Cir. 1998). Holding that this "fraud-on-the-FDA" claim was preempted, this Court stated: "The conflict stems from the fact that the

federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Buckman*, 531 U.S. at 348. Summing up its reasoning, the Court stated: "[W]ere plaintiffs to maintain their fraud-on-the agency claims here, they would not be relying on traditional state tort law [that] had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case." *Id.* at 353.

The same cannot be said here. First, respondents' claims, if successful, would not "punish and deter fraud against" the FDA. Rather, as in *Medtronic*, respondents' claims "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not from the violation of FDCA requirements." *Id.* at 352. Second, the claims at issue existed prior to the FDCA and exist apart from the FDCA. The complaints do allege that Rezulin would not have been approved for sale if Warner-Lambert had not concealed from or misrepresented information to the FDA, but those allegations are for the purpose of rebutting the defense provided by § 600.2946(5), not for the purpose of seeking to impose liability for fraud on the agency. That is, the company's conduct with respect to the agency is at issue in the case, not because of the common-law claims alleged, but because the company has asserted FDA approval as a defense to liability under state law. *See Taylor*, 658 N.W.2d at 131 (§ 600.2946(5) provides defense to product liability claim). *Buckman* simply does not address this situation.

Warner-Lambert (at 45) incorrectly suggests that the elements of the claim alleged in *Buckman* "mirror" the elements that respondents must prove to prevail in their lawsuits here. In *Buckman*, however, the plaintiffs did not allege or seek to prove against Buckman the traditional elements of a common-law tort claim—a design defect, a failure to provide adequate warnings about risks associated with product, or a breach of warranty. Here, by contrast, respondents will not prevail unless they can prove the elements of those traditional claims —including existence of the relevant duties, breach of the duties, and injury resulting from the particular defects or breaches. *See* Pet. App. 336a, 343a, 353a; JA 35-38, 43.

Accordingly, a finding that the company had obtained FDA approval for Rezulin through misrepresentation or omission would not, as in *Buckman*, be a finding of liability. Rather, its effect would be only to put the case back in the position it would have been in had Warner-Lambert not invoked § 600.2946(5). For this reason, the concerns articulated in *Buckman*—that only the FDA should have responsibility for policing its approval process and for determining the appropriate sanction for failures to comply with FDA requirements—do not apply here.

B. The Exception To Michigan's Statutory Defense Is Not Impliedly Preempted.

That *Buckman* does not control here does not fully answer the question whether respondents' rebuttal to Warner-Lambert's FDA-compliance defense is preempted. The answer to that question is no. Warner-Lambert contends, however, first, that the FDA occupies the field of regulating compliance with federal disclosure obligations and that the Michigan statute

intrudes on this field, and, second, that the Michigan statute presents an obstacle to the uniform enforcement of the FDCA. Neither contention is correct.

1. Warner-Lambert argues that only the FDA can enforce compliance with the disclosure obligations imposed on drug companies, and that Michigan law requires three showings that intrude on the FDA's "field": (1) a showing of what Warner-Lambert was required to disclose to the FDA under the relevant federal standards, (2) a showing that the company failed to submit or misrepresented information required under the FDCA and applicable regulations, and (3) a showing that the FDA would not have approved the drug or would have withdrawn approval if the company had not withheld the information. According to Warner-Lambert (at 25, 28), each of these three showings is preempted because each involves the interpretation and application of federal statutes and regulations that are subject to exclusive federal oversight.

To begin with, this Court has long recognized the viability of state-law claims premised on the failure to comply with federal regulations. Thus, for example, in *Bates*, the Court unanimously held that "States are free to impose liability predicated on a violation of the federal standards" set forth in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). *Bates*, 544 U.S. at 455 (Thomas, J., concurring in part and dissenting in part); *accord id.* at 447 (majority opinion). And the Court explained that a state-law duty equivalent to a federal duty "need not be phrased in identical language as its corresponding [federal] requirement." *Id.* at 454. Likewise, in *Medtronic*, the Court unanimously held that state-law claims that seek to enforce common-law requirements that parallel federal requirements are not preempted under the express preemption provision

of the Medical Device Amendments of 1976. 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

Although these cases involved interpretation of express preemption provisions, they are relevant here because one cannot show that state and federal requirements are equivalent without showing what the federal requirements are and what the defendant was required to do to satisfy them. Yet in neither case did the Court express any concern that such a showing would intrude on an occupied federal field or pose an obstacle to the operation of the federal regulatory scheme. To the contrary, in *Medtronic*, Justice O'Connor observed that "[w]here a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement 'different from or in addition to' requirements under federal law," and she noted no concern about the continued viability of such state-law claims. 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part); *see id.* at 495 (majority opinion). And in *Bates*, the Court observed that "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of" the Federal Insecticide, Fungicide, and Rodenticide Act. 544 U.S. at 451.

Second, states have long allowed negligence per se claims premised on violations of federal law—which is essentially what *Bates* and *Medtronic* countenanced—and those claims necessarily require showing both what the federal requirements are and whether the defendant-company satisfied them. This Court, however, has expressed no concern about any "intrusive" effects of such claims. For example, in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308 (2005), the Court noted that "in garden variety state tort

law," "[t]he violation of federal statutes and regulations is commonly given negligence per se effect." *Id.* at 318 (citing *Restatement (Third) of Torts* § 14, Reporters' Note, p.195 cmt. a, Tent. Draft No.1 (Mar. 28, 2001)). And the Court noted that some states "treat a violation of a federal statute as evidence of negligence or . . . as creating a rebuttable presumption of negligence. Either approach could still implicate issues of federal law." *Id.* at 319 n.6 (citation omitted). While recognizing the "garden variety" nature of these claims, the Court expressed no concern about their viability or effect on the federal regulatory schemes. *See also Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804 (1986) (negligence per se claim against drug manufacturer based on manufacturer's violation of FDCA).[6]

Similarly, some federal-law cases require the sort of findings that Warner-Lambert contends intrude on the FDA's exclusive domain. For example, juries make fact findings in criminal prosecutions for violations of the FDCA and in civil cases stemming from FDA enforcement actions. *See* 21 U.S.C. §§ 331(b), 332, 334(b). And in patent litigation between private parties, a patent may be held unenforceable based on the holder's "inequitable conduct," a judicially created doctrine that turns

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[6]In *Merrell Dow*, which rejected federal question jurisdiction over a negligence per se claim premised on a violation of the FDCA, the Court noted that the petitioner's argument was, in effect, that the FDCA preempted state-court jurisdiction over the dispute. However, the Court quickly dismissed that argument. 478 U.S. at 815 & n.13. The dissenting Justices suggested that a negligence per se claim might be preempted, not because the claim would interfere with FDA regulation, but because a decision by Congress not to create a private cause of action might be intended to preclude private enforcement. *Id.* at 831 (Brennan, J., dissenting). *Bates* and *Medtronic* effectively—and unanimously—reject that suggestion.

on factual findings that the holder failed to disclose material information or submitted false material information with an intent to mislead the Patent and Trademark Office. *See Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1332 (Fed. Cir. 2006); *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

Third, the Michigan statute only comes into play when the manufacturer asserts that it received FDA approval to market its drug and that it complied with the terms of that approval at the time the drug left its control. Mich. Comp. Laws § 600.2946(5). But to show that it complied with the terms of approval, the manufacturer must first show what obligations the FDA and the FDCA imposed on it when its drug was approved, and then show that it complied with those obligations. *See, e.g.*, Pet. Br. 13-14; *see also* Letter from FDA to Parke-Davis Pharmaceutical Research (Rezulin approval letter), *supra* p. 6 ("you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 [postmarketing reporting of adverse drug experiences] and 314.81 [other postmarketing reports]"). These showings, however, address the same topics as the first two showings that Warner-Lambert argues invade the federal field. Thus, it is the manufacturer, not the plaintiff, that in the first instance imports into the litigation the first two showings challenged by Warner-Lambert. If preemption bars a plaintiff's showing on these elements of the rebuttal to the Michigan statutory defense, then it must also preempt a defendant's showing that the defense applies. Conversely, if the defendant's compliance defense is not preempted—as the parties to this case and the United States assume—then those two aspects of the plaintiff's rebuttal are not preempted either.

Moreover, as noted above, every state allows a manufacturer to offer evidence of compliance with federal standards to show non-defect or non-negligence, although in the "overwhelming majority of jurisdictions" the evidence is not dispositive. *Restatement (Third)* § 4 Reporters' Note, cmt. e; *accord* 63B Am. Jur. 2d *Prods. Liab.* § 2022 (2007) ("As a general rule, compliance with applicable federal standards is relevant but not conclusive evidence in a products liability case.").[7] Therefore, if Warner-Lambert were correct that evidence about the relevant federal requirements and whether the defendant complied with those requirements improperly intrudes on the FDA's exclusive domain, defendants would lose the ability to present an important defense in product liability cases involving not only drugs, but also other regulated products, including pesticides, automobiles, and medical devices, and not only in Michigan cases, but in cases across the country.

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[7] *See, e.g., Howard v. McCrory Corp.*, 601 F.2d 133, 138 & n.9 (4th Cir. 1979) (Maryland law); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1974) (North Carolina law); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024 (D.N.J. 1988); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M. 1995); *Banks v. ICI Americas, Inc .*, 450 S.E.2d 671, 675 n.6 (Ga. 1994); *Wagner v. Clark Equip. Co.*, 700 A.2d 38, 50 (Conn. 1997); *Toner v. Lederle Labs.*, 732 P.2d 297, 311 n.12 (Idaho 1987); *Zacher v. Budd Co.*, 396 N.W.2d 122, 133-34 (S.D. 1986); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70-71 (Mass. 1985); *Gable v. Gates Mills*, 784 N.E.2d 739, 748-49 (Ohio App. 2003); *Asbestos v. Bordelon, Inc.*, 726 So. 2d 926, 958 (La. App. 1998); *Hernandez v. Badger Constr. Equip. Co.*, 34 Cal. Rptr. 2d 732, 756 (Cal. Ct. App. 1994); *Bennett v. Mallinckrodt, Inc .*, 698 S.W.2d 854, 859 (Mo. App. 1985); *Malek v. Lederle Labs.*, 466 N.E.2d 1038, 1040 (Ill. App. 1984); *Shell Oil Co. v. Gutierrez*, 581 P.2d 271, 279-80 (Ariz. App. 1978); *Sherman v. M. Lowenstein & Sons, Inc.*, 282 N.Y.S.2d 142, 143-44 (N.Y. App. Div. 1967); Ind. Code § 34-20-5-1; Kan. Stat. Ann. § 60-3304(a); Tenn. Code Ann. § 29-28-104; Utah Code Ann. § 78-15-6.

Warner-Lambert's argument thus has very broad ramifications. Adopting it would turn the product liability law of every state upside-down by precluding not only plaintiffs' rebuttal to evidence of compliance with federal standards but the compliance defense itself.

As for the third enumerated showing—whether the failure to disclose was material to the FDA's approval—Warner-Lambert argues (at 26) that it is preempted because its "only effect" is to police and enforce compliance with FDA disclosure rules. Warner-Lambert is incorrect. Rather, as the Second Circuit explained, Pet. App. 18a n.5, the legislation's principal effect is (and the reason for its passage was) to reduce manufacturers' tort liability in light of a perceived increase in product liability litigation.[8] Like the exception for instances in which the drug's approval was tainted by bribery, *see* Mich. Comp. Laws § 600.2946(5)(b), the exception for instances in which the drug manufacturer obtained or maintained approval without complying with disclosure requirements does not function to police the regulatory process, but rather to ensure that the defense otherwise conferred under the new law does not extend to circumstances in which the state has insufficient confidence in the agency's approval to accord it dispositive legal weight. Yet even in those circumstances, far from punishing manufacturers, this element of the Michigan law provides that the defense is still available if the company's non-disclosure was not material.

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[8]There are no legislative reports on § 600.2946(5). The statute derived from a state senate bill, and the "Bill Analysis" by the Senate Fiscal Agency shows that the legislation was based the perception of an "explosion" in product liability litigation. Pet. App. 18a n.5 (quoting S. Fiscal Agency, SFA B. Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at *1 (Jan. 11, 1996)).

For the same reason, the premise of Warner-Lambert's field preemption argument—that only the FDA can decide whether or not to enforce its regulations—is inapposite here. In *Buckman*, the plaintiffs sought damages *for* violation of federal law, based on an alleged causal connection between the violation of FDA requirements and the injury suffered. In contrast, § 600.2946(5) does not seek to enforce FDA requirements, and it does not punish manufacturers for noncompliance. Indeed, even where the manufacturer's non-disclosure did affect the FDA's decisionmaking, Michigan makes clear that the state does not seek to punish the company by providing that noncompliance with federal regulations "does *not* raise a presumption of negligence." Mich. Comp. Laws § 600.2946(4) (emphasis added). The Michigan statute simply provides that, as a matter of state law, manufacturers that complied with the requirements of FDA approval, including disclosure requirements, cannot be held liable in a product liability action, and manufacturers that did not comply with disclosure requirements can be—but only if they are otherwise liable under state common-law principles.

Put differently, respondents seek to impose liability because Warner-Lambert defectively designed its product and failed to warn of serious dangers inherent in its use. Because Warner-Lambert had obtained FDA approval to market Rezulin, respondents can pursue their claims under Michigan law only *if* the company made material misrepresentations to the FDA, but, unlike in *Buckman*, they are not seeking to impose liability *because* of those misrepresentations.

In this regard, the Michigan statute reflects not only the traditional rule allowing manufacturers to use regulatory compliance as evidence of non-defect; it also

reflects the traditional rule that when the approval process "was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that . . . approved the product, compliance with regulation is entitled to little or no weight." *Restatement (Third)* § 4 cmt. e; *cf.* 63B Am. Jur. 2d *Prods. Liab.* § 2022 (to be admissible as evidence of due care, federal safety standards for consumer products "must meet the threshold evidentiary showing of trustworthiness"). Indeed, the two are not distinct rules, but part and parcel of a single approach to the role of regulatory compliance in product liability cases. When a court has no confidence that the regulatory process "was full, fair, and thorough and reflected substantial expertise," *id.*, the basis for giving weight to the approval—not to mention dispositive weight—evaporates. The legislature's decision to withhold a defense in these circumstances does not intrude on the FDA's enforcement authority.

2. Warner-Lambert also argues that a determination that § 600.2946(5)(a) was satisfied—that is, that the FDA would not have approved Rezulin or would have withdrawn approval sooner if the company had not misrepresented or omitted relevant information—poses an obstacle to uniform enforcement of the FDCA. Warner-Lambert concedes that this conflict preemption argument is not really distinct from its field preemption argument, *see* Pet. Br. 21-22 & n.9, and its discussion of conflict preemption largely repeats arguments made elsewhere in its brief.

Nonetheless, in the guise of discussing conflict preemption, Warner-Lambert makes a few additional arguments. First, the company points out that the FDA never made a finding of fraud. Although that point is correct, Warner-Lambert fails to note that the FDA

rarely if ever makes such findings. *See* U.S. Br. 24 n.7 (citing 2 cases from past 10 years). Thus, the contention that a Michigan determination on this point would intrude on the FDA's "core functions," Pet. Br. 30, falls wide of the mark. Instead, as the United States explains, fraud investigations would divert resources from the agency's "core public health mission." U.S. Br. 24.

Warner-Lambert also argues that allowing findings about what the FDA would have done if the company's submissions had not misrepresented or omitted relevant information would upset "the delicate balance of statutory objectives" implicated in FDA decisionmaking. Pet. Br. 31 (quoting *Buckman*, 531 U.S. at 348). However, in the passage of *Buckman* quoted by Warner-Lambert, the Court was not discussing the effect on federal regulation of a litigation finding that the FDA would have made a different decision if the company had been honest with it. The Court was discussing the balance of objectives that the agency achieves through exercise of its power to punish and deter fraud against it, which the Court held could be "skewed" by allowing state-law liability for fraud on the FDA. Here, as discussed above, respondents are not seeking to hold Warner-Lambert liable for withholding information from and lying to the agency; their showing in this regard is aimed only at getting past Warner-Lambert's statutory defense so that they can litigate the question of liability based on traditional common-law elements.

Accordingly, cases cited by Warner-Lambert for the proposition that factfinders should not be able to "reformulate . . . technical balances reached by agencies," Pet. Br. 31, do not apply here. For example, in *Geier*, 529 U.S. at 881, cited by Warner-Lambert, the Court held that a claim seeking damages against an automaker for

failure to install an airbag was preempted, where the automaker had complied with a federal regulation that expressly provided automakers a choice about whether to install airbags because the agency sought a gradual phase-in of passive restraint devices. In *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 714 (1984), the Court held a state regulation prohibiting certain advertisements on cable television was preempted because the state "requirements directly conflict with" the agency's unambiguously expressed intent to preempt state regulation of signals carried by cable television systems. And in *Ray v. Atlantic Richfield*, 435 U.S. 151, 177 (1978), the Court held that federal regulation imposing size limitations on oil tankers preempted a more stringent Washington State regulation on this same topic. Here, the wisdom of a federal regulation is not at issue; Warner-Lambert does not allege a "direct conflict" of the sort at issue in *Capital Cities* and *Ray*, and the Michigan law does not ask factfinders to rethink a regulatory balance struck by the agency. Rather, the premise of § 600.2946(5) is that the balance struck by the agency's regulations is the right one.

Both Warner-Lambert and the United States argue that the showing under § 600.2946(5)(a) is preempted because a judge or jury should not be allowed to predict what the FDA would have done if Warner-Lambert had submitted accurate information. Although both rely on rely *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981) ("*Arkla*"), that case is inapposite. There, an award of damages would have effectively afforded the plaintiff a retroactive change in a filed rate for natural gas. However, the Natural Gas Act authorized only the Federal Power Commission to change rates and prohibited even the Commission from doing so retroactively. On this basis, the damages suit was held to

conflict with the Act. In contrast, the FDCA does not concern economic regulation of the drug and medical device industries. And whereas in *Arkla* the damages sought would have had an effect forbidden under the federal statute (a retroactive change in rates), the damages sought here (as in tort cases brought against drug companies in other states) would have no effect, retroactive or otherwise, on marketing approval under the FDCA.

The United States also cites *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981), but that case is not on point either. In *Kalo Brick*, the petitioner had sought and obtained permission from the Interstate Commerce Commission ("ICC") to stop rail service on a certain line. When the service stopped, the respondent sued the petitioner for damages resulting from the cessation of service. The Court held that the lawsuit was preempted because it required the state court to evaluate the reasonableness of closing the line, an evaluation Congress had assigned to the ICC. The Court pointed out that the Interstate Commerce Act offered administrative remedies but that the respondent had not availed itself of those remedies. Although the Act did not offer a private damages remedy, the available administrative remedies would have allowed the respondent to object to and seek reversal of the agency decision allowing cessation of service.

In contrast, here, respondents had no administrative remedies to pursue. Petitioning the FDA to remove Rezulin from the market would not remedy or ameliorate the liver injuries already suffered by respondents; and, besides, Rezulin has been off the market since March 2000. Furthermore, at the time of Rezulin's approval, patients had no basis for objecting to or

seeking reversal of the FDA's approval decision because they could not have known then that their physicians would prescribe Rezulin and that they would suffer injury as a result. Moreover, *Kalo Brick* left open the question whether a state-law claim would be preempted if the federal agency were empowered to rule on an issue but had not done so. *Id.* at 327 ("But we need not decide whether a state-court suit is barred when the Commission is empowered to rule on the underlying issues, because here the Commission has actually addressed the matters respondent wishes to raise in state court."). Here, as the United States's brief emphasizes (at 5, 21), the FDA has never made a finding about whether its approval decision would have been different if the company had not misrepresented and omitted information about adverse events, and the agency is not intending to do so.

Although the United States makes a brief plea for deference, U.S. Br. 25, its view is not entitled to weight here because the statement of the agency's position lacks the requisite formality. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference due to government depends on, among other things, formality and consistency of government's position). The United States relies on *Medtronic*, 518 U.S. at 496, but that case does not support deference to the position stated in the government's brief in this case. In *Medtronic*, the Court was interpreting the scope of an express preemption provision and deferred to the agency's *regulation*—not to its amicus brief—because of the "unique role" that Congress gave the agency in determining the scope of preemption, as exhibited by both the particular language of the preemption provision and a related provision giving the FDA authority to exempt certain state laws from preemption.

Id. (citing 21 U.S.C. § 360k(a) & (b)). In contrast, here, the United States seeks deference to the position stated in an amicus brief, not to an FDA regulation, and no statutory provision exists giving the FDA a direct role in interpreting the scope of preemption in this context.

In addition, deference is unwarranted because, just last year, the United States advocated a contrary position. *See Mead Corp.*, 533 U.S. at 228. In a failure-to-warn case brought by the parents of an injured child against a prescription drug manufacturer, the FDA argued that a judge presiding in such a case should begin by making the determination whether the FDA would have rejected the warning sought by the plaintiff on the ground that it would render the product misbranded or that it was unsubstantiated. Br. of U.S. as Amicus Curiae at 11, *Perry v. Novartis Pharms.* , 456 U.S. 678 (E.D. Pa. 2006) (Civ. No. 05-5350). The FDA stated that determining whether tort liability for failure to warn would conflict with the accomplishment of federal objectives "require[s] an analysis of the agency's actions and the actions that are alleged to give rise to liability." *Id.* And the FDA suggested that "the court must ask" how the agency would have reacted if the company had proposed a particular warning. *Id.* In other words, just last year, the FDA argued that, in tort cases against drug manufacturers, courts *must* make findings about how the FDA would have reacted if a manufacturer had presented it with different information (there, a new warning and information to support it). For this reason as well, the United States's argument here that such findings conflict with the federal regulatory scheme deserves no weight. *See Bates*, 544 U.S. at 449, 451-52 (giving no weight to agency's view on preemption in light of agency's flip-flop).

3. Warner-Lambert also argues that allowing litigation to address the findings required to rebut the Michigan defense would increase burdens on manufacturers. Yet, as discussed above, the product liability law of every state allows defendants to present evidence of federal compliance as a defense and allows plaintiffs to present evidence to counter that defense, and this traditional tort-law scheme would seem to create the same burdens and incentives that Warner-Lambert purports to fear from the Michigan statute. Throughout the nearly 70 years during which the FDA has regulated the marketing of prescription drugs, drug companies have not only survived but prospered in the face of any burdens posed by tort law. In any event, the company does not argue that state and federal law impose inconsistent burdens on manufacturers, and thus its argument on this point is not a basis for preemption.

In a related argument, Warner-Lambert contends that the exception to the Michigan statute "would" encourage companies to submit to the FDA large amounts of information that the FDA "neither wants nor needs." Pet. Br. 27 (quoting *Buckman*, 531 U.S. at 351). The Michigan statute, however, has been in effect since 1995 (and the Sixth Circuit did not issue its decision in *Garcia* holding the exception usually preempted until 2004); four states passed statutes immunizing manufacturers of approved prescription drugs from punitive damages unless the plaintiff could show that the company made misrepresentations or failed to submit relevant information to the FDA in 1987, and two others passed similar statutes in 1989.[9] Warner-Lambert offers

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[9]Ariz. Rev. State. Ann. § 12-701 (enacted in 1989); N.D. Cent. Code § 32-03.2-11 (enacted in 1987); N.J. Stat. Ann. § 2A:58C-5(c) (continued...)

no evidence that the FDA is receiving excessive and unwanted quantities of information attributable to these laws. Moreover, the Food and Drug Administration Amendments Act of 2007 requires drug companies to provide information about clinical trials and their results in a publicly accessible registry. *See* Pub. L. No. 110-85, § 801, *to be codified at* 42 U.S.C. § 282. The public's increased access to this information greatly alleviates any concern about how plaintiffs will prove what information a drug manufacturer had and whether it disclosed this information.

Furthermore, the exception expressly applies only to non-disclosure of information that is "*required* to be submitted under the [FDCA]." Mich. Comp. Laws § 600.2946(5)(a). In addition, the exception is limited to instances where non-disclosure had a demonstrable effect on FDA decisionmaking. *Id.* Both of these features ensure that the statute does not encourage manufacturers to flood the FDA with immaterial information because submission of such information would not help a manufacturer to defend against the non-compliance exception. And again, unless such submissions interfere with the agency's ability to accomplish its objectives, this contention is not a basis for preemption. Warner-Lambert cites *Buckman* for this point, but there, the Court noted that "a deluge of information that the [FDA] neither wants nor needs" could delay the streamlined 510(k) review process. 531 U.S. at 351. That statement does not apply here, where the NDA process is not "comparatively speedy," *id.*, and

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[9](...continued)
(enacted in 1987); Ohio Rev. Code Ann. § 2307.80 (enacted in 1987); Or. Rev. Stat. § 30.927 (enacted in 1987); Utah Code Ann. § 78-18-2 (enacted in 1989).

requires far more significant submissions. *See supra* p. 3; Pet. Br. 5 & n.1.

Warner-Lambert suggests that juries cannot be trusted to distinguish immaterial omissions from material ones, but its distrust is an insufficient basis for ousting state law. Juries make fact findings in criminal prosecutions and civil cases arising from FDA enforcement actions, as discussed above. *See supra* p. 26; *cf. Bates*, 544 U.S. at 452 ("[L]ay juries are in no sense anathema to FIFRA's scheme: In criminal prosecutions for violations of FIFRA's provisions, juries necessarily pass on allegations of misbranding.") (citation omitted). Furthermore, drug companies, even some who sold notoriously dangerous products, are often able to prevail in jury trials. *See, e.g.*, Associated Press, *Major victory for Merck in N.J. Vioxx trial* (Nov. 3, 2005), *available at* http://www.msnbc.msn.com/id/9910674/. And Warner-Lambert's insinuation that juries are improperly swayed by plaintiffs' arguments and cannot be trusted to evaluate evidence objectively is refuted by Department of Justice statistics, which show that plaintiffs win only 44 percent of state-court trials in product liability cases and 43 percent of federal-court trials in such cases. DOJ Bureau of Justice Statistics, *Tort Trials and Verdicts in Large Counties, 2001*, at 4 Table 3 (Nov. 2004); DOJ Bureau of Justice Statistics, *Federal Tort Trials and Verdicts, 2002-03*, at 1 (Aug. 2005).[10]

The history of tort litigation against drug manufacturers also belies the theory that the Michigan statute will distort FDA decisionmaking or burden FDA

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[10]The Bureau of Justice Statistics reports are available at http://www.ojp.usdoj.gov/bjs/pub/pdf/ttvlc01.pdf and http://www.ojp.usdoj.gov/bjs/pub/pdf/fttv03.pdf.

personnel who are asked to testify in product liability cases. Tort litigation against drug companies has co-existed with the FDCA since 1938. And the "overwhelming majority of jurisdictions hold that compliance with product safety regulation is relevant and admissible on the question of defectiveness, but is not necessarily controlling." *Restatement (Third)* § 4 Reporters' Note, cmt. e. The Restatement (Second) took a similar approach. *Restatement (Second) of Torts* § 288C (1965) ("Compliance with . . . an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions."). Yet neither Warner-Lambert nor the United States has offered evidence suggesting that the FDA's ability to fulfill its mission has been adversely affected by state tort litigation. To be sure, the Michigan statute has an additional element not found in other jurisdictions—the showing of how the FDA would have reacted to the information if properly disclosed. Yet it is not obvious why that additional element would add a burden not posed by the traditional compliance defense, or why the plaintiffs would try to force current FDA medical officers to testify, presumably against the FDA's wishes, when there are so many former FDA medical officers potentially available. *See* FDA, *FDA Science and Mission at Risk, Report of the Subcomm. on Science and Technology* at 4 (Nov. 30, 2007) (discussing unusually high turnover rate in FDA science staff). In sum, evidence about the existence of federal standards and approvals, and argument about compliance with standards and conditions of approval, have long been a part of product liability litigation.[11]

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[11]Although Warner-Lambert states that the Court need not address the question whether the Michigan provision would be

(continued...)

Accordingly, the consequences of adopting Warner-Lambert's preemption argument would be far broader than the effect on the Michigan statute and would threaten principles of product liability law in every state—principles that benefit both plaintiffs and defendants. As the court below stated, adopting Warner-Lambert's view "would result in preemption of a scope that would go far beyond anything that has been applied in the past." Pet. App. 24a. But for the reasons explained above, Warner-Lambert's view is incorrect, and the decision below should be affirmed.

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[11](...continued)
preempted if the FDA had made a fraud finding, the United States (at 23-24) argues that preemption would bar a plaintiff's showing under the Michigan statute *even if* the FDA had found fraud. The United States's argument on this point is *not* that the Michigan statute would, in such instances, conflict with any FDA determination or intrude on the FDA's judgment about how to enforce its regulations. Rather, it argues that, as a practical matter, allowing injured patients to rely on FDA fraud findings to get past the hurdle imposed by § 600.2946(5) *might* motivate potential plaintiffs to file citizen petitions asking the FDA to make fraud findings, which the FDA does not typically make, and that processing such petitions would be burdensome. The United States does not explain the connection between these speculative concerns and the preemption doctrine. After all, federal law affirmatively allows citizens to file such petitions. *See* 5 U.S.C. § 553(e); 21 C.F.R. § 10.30. Moreover, the FDA's purported concerns are unfounded. More than three years ago, the Sixth Circuit held that § 600.2946(5)(a) is preempted except when the FDA has made a finding of fraud. *Garcia*, 385 F.3d at 966. Notably, the United States does not offer any evidence of a deluge of citizen petitions—or *any* citizen petitions—filed since then by Michigan patients requesting that the FDA make such findings.

III. IF THE COURT HOLDS THAT SOME OR ALL OF § 600.2946(5)(a) IS PREEMPTED, THE CASE SHOULD BE REMANDED FOR CONSIDERATION OF SEVERABILITY.

The decision below is correct and should be affirmed. However, if the Court disagrees, this case must be remanded to the Second Circuit for consideration of whether the preempted portion of the statute is severable. For example, if this Court holds that the final clauses of paragraph (a), which require a finding about how the FDA would have reacted to an honest submission, are preempted, the lower court must determine whether those clauses are severable from the remainder of paragraph (a) and/or from subsection (5) in its entirety. If this Court holds that all of paragraph (a) is preempted, the lower court must determine whether paragraph (a) is severable from the rest of subsection (5) or whether all of subsection (5) is therefore invalid. Severability was briefed and argued below, but because the Second Circuit held that no part of paragraph (a) is preempted, it did not reach the issue.

Michigan law, through Mich. Comp. Laws § 8.5, expressly addresses severability, explaining that a determination that one portion of an act is invalid will not invalidate remaining portions that can nonetheless be given effect. "To be capable of separate enforcement, the valid portion of the statute must be independent of the invalid sections, forming a complete act within itself. After separation of the valid parts of the enactment, the law enforced must be reasonable in view of the act as originally drafted." *Pletz v. Sec'y of State*, 336 N.W.2d 789, 809 (Mich. App. 1983) (severing invalid portions of statute where remainder consistent with intent of the legislature); *see also Maki v. East Tawas*, 188 N.W. 2d 592, 595 & n.1 (Mich. 1971) (striking

down, rather than limiting scope of, statutory provision where "we cannot determine how [the legislature] would have voted had they" faced the choice). Because the severability question that will arise here if the Court finds some or all of paragraph (a) preempted is a question of state law, a remand would be required to allow the lower court to address the issue or, possibly, to certify the question to the Michigan Supreme Court.

Below, Warner-Lambert relied primarily on *Garcia* as support for the argument that paragraph (a) of § 600.2946(5) is severable, and it urged the Second Circuit to defer to that Sixth Circuit decision. That argument, which Warner-Lambert reprises very briefly here, *see* Pet. Br. 50 n.18, is insufficient to avoid a remand for four reasons. First, Warner-Lambert did not include severability in the question presented, and thus the severability issue, including whether *Garcia* binds either this Court or the Second Circuit on this point, is not before the Court.

Second, Warner-Lambert (at 50 n.18) cites cases for the proposition that this Court usually defers to or "leaves undisturbed" the decision of a regional court of appeals on a state-law issue where a case comes to the Court from that court of appeals. It cites no authority for reversing a court of appeals' decision based on another court's state-law ruling in another case.

Third, the argument about whether the Second Circuit should or would defer to the Sixth Circuit is based largely on interpretation and application of a Second Circuit case, *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981). In that case, the Second Circuit deferred to a state-law holding of a federal court of appeals in which the relevant state was located, but noted that the holding was not binding because the

ultimate source of authority for adjudicating state-law issues in diversity cases "is the law as established by the constitution, statutes, or authoritative court decisions of the state." *Id.* at 283. The degree to which one federal court of appeals (or this Court) should defer to another on a question of state law is not fairly encompassed in the question presented here, yet Warner-Lambert's primary argument in favor of severability would require resolution of this question. The Second Circuit's case law gives ample deference to the views of the home circuit, and that court can give the Sixth Circuit's views any weight that the Second Circuit determines it deserves. The case should be remanded to enable the Second Circuit to apply its law in the first instance.

Fourth, *Garcia*'s consideration of severability was based on its own conclusion about the scope of pre-emption. Specifically, *Garcia* had held that all of paragraph (a) is preempted, except where the FDA has made a finding of fraud. 385 F.3d at 966. Below, Warner-Lambert argued that this holding was correct. *See* Br. for Appellees, No. 05-1705(L) at 28 n.10, filed July 27, 2005. Here, Warner-Lambert urges the Court not to address whether the Michigan law is preempted in circumstances where the FDA has found that the company made material representations that affected the FDA's decisionmaking. Pet. Br. 37. And the United States urges the Court to hold the statute preempted even in such cases. U.S. Br. 23. Unless the Court addresses this circumstance and agrees with *Garcia* on the point, there will be no basis for deferring to the Sixth Circuit's holding on severability, for the Sixth Circuit did not address the question whether § 600.2946(5) can survive without any exception for instances where the FDA has actually made a finding of fraud. Similarly, if the Court holds that the portion of

paragraph (a) that requires a finding about what the FDA would have done if presented with accurate information is preempted, but that the rest of paragraph (a) is not preempted, its preemption holding will differ from the holding in *Garcia*. In that circumstance as well, there will be no basis for deferring to the Sixth Circuit's holding on severability, premised on a different conclusion about the scope of preemption.

Finally, if paragraph (a) is preempted in its entirety, it is not severable from the remainder of the statute. Michigan enacted § 600.2946(5) to reduce the amount of product liability litigation against drug manufacturers, but, at the same time, the state legislature made clear, through the plain language of the statute, that it did not want to extend immunity in cases where the drug approval was tainted. Therefore, through two exceptions—one for drug manufacturers who misrepresented information to or omitted information from the FDA (paragraph (a)) and one for manufacturers who bribed an FDA official (paragraph (b))—the legislature withheld the statutory defense from manufacturers who obtained or maintained marketing approval through dishonest means. To sever one exception from the statute, thereby conferring irrebutable immunity on a category of manufacturers that the legislature plainly did not intend to protect, would not be "reasonable in view of the act as originally drafted." *Pletz*, 336 N.W.2d at 809.

CONCLUSION

The decision of the United States Court of Appeals for the Second Circuit should be affirmed.

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No. 06-1498

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC AND PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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INTRODUCTION

Contrary to the suggestion of respondents and their *amici*, the preemption question presented here is quite narrow. Petitioners are not asking the Court to decide the relationship between FDA law generally and state-law tort liability. Those are issues the Court will confront elsewhere (see note 1, *infra*). Here the question is whether state courts have authority to adjudicate, as a predicate to assessing state tort liability against a manufacturer of a regulated pharmaceutical, claims that FDA was defrauded and would have ordered the drug withdrawn when, in fact, (i) FDA has found no such fraud, and (ii) the product was withdrawn for reasons independent of any purported fraud. This Court already has said that the answer to that question is: no. The Michigan exception requires the same state-law fraud-on-the-FDA determinations this Court held were preempted in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Respondents do not dispute that the Michigan exception requires a state-law determination of the same essential elements as in *Buckman*. See, *e.g.*, Resp. Br. 10, 14-15. Moreover, respondents acknowledge that "FDA never made a finding of fraud" in the Rezulin regulatory process, *id.* at 31, and "is not intending to do so," *id.* at 35. Indeed, the United States confirms that FDA has never found fraud relating to its regulation of Rezulin, U.S. Br. 5, 21, and "did not . . . rely on a finding of fraud" when it asked Warner-Lambert to withdraw the drug from the market, *id.* at 21. Nonetheless, respondents contend that state law is entitled to superintend this federal domain and allow a lay jury to speculate that the company actually committed fraud with respect

to its disclosure duties to FDA that caused FDA to withdraw Rezulin from the market. Respondents not only suggest that a jury *may* substitute its view for what FDA actually did; their theory of recovery in this case *demands* it.

Thus, although respondents paint their theories with a broad brush, the critical point here is that Rezulin was not withdrawn on account of fraud-on-the-FDA. See, *e.g.*, U.S. Br. 5, 21; Resp. Br. 31, 35 (acknowledging that FDA neither withdrew the drug due to fraud, nor made a finding that the agency was defrauded). Rather, Rezulin was withdrawn because it was a first-generation drug that later became "outmoded," by two newer diabetes medications. Ctr. for Drug Evaluation & Research ("CDER"), FDA, *Meeting No. 74 of Endocrinologic & Metabolic Drugs Advisory Committee* ("EMDAC Tr.") 82-83 (May 19, 2000), *available at* http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3615t1.pdf.

Contrary to respondents' insinuation, the regulatory process worked with respect to Rezulin. When Rezulin was approved, it was the first in a new class of medications that targeted insulin resistance, an underlying cause of Type 2 diabetes—a life-threatening disease affecting 18 million Americans. Pet. Br. 13; U.S. Br. 4. FDA determined that the overall risk-benefit profile made Rezulin a worthwhile treatment option for many patients suffering from this serious condition. FDA also was acutely aware "since 1997" (when the drug was approved) of a potential risk of "[s]evere liver toxicity"—a fact FDA has explicitly acknowledged. See Pet. Br. 14 (alteration in original) (quoting HHS press release). Several years later, FDA approved two new second-generation drugs targeting insulin resistance. Because these newer drugs "offer[ed] a similar

benefit" as Rezulin with a decreased risk of liver toxicity, Warner-Lambert voluntarily discontinued marketing Rezulin and asked FDA to withdraw its approval of the drug. Notice of Withdrawal of Approval of a New Drug Application, 68 Fed. Reg. 1469, 1469 (Jan. 10, 2003). Thus, the record is clear that FDA did not withdraw its approval of Rezulin because of any finding of misconduct on the part of the manufacturer. See EMDAC Tr. 82-83; 68 Fed. Reg. at 1469; Pet. Br. 14-15; U.S. Br. 21 (FDA did not "rely on a finding of fraud" in withdrawing Rezulin).

Even though the agency has not found that petitioners materially breached any duty to it, respondents' claims would require a contrary state-law determination—*i.e.*, that petitioners defrauded FDA and that FDA withdrew Rezulin from the market on account of that purported fraud. Mich. Comp. Laws § 600.2946(5)(a) (requiring proof that the manufacturer "intentionally withh[eld] from or misrepresent[ed] to [FDA] information concerning the drug that is required to be submitted under the federal food, drug and cosmetic act [citing FDCA provisions], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted"). This attempt to inject state law into the limited, but exclusively, federal domain concerning the enforcement of duties owed to FDA by regulated entities is preempted. As *Buckman* teaches, because of the exquisitely complex scientific and public health issues FDA must balance, juries applying state law are not free to second-guess this federal process and substitute their view of what FDA might have done for what the agency *actually* did. See *Buckman*, 531 U.S. at 347-48; *id.* at 354 (Stevens, J., concurring in judgment) (preemption applies where jury is

required, as here, to "speculat[e] as to the FDA's behavior" and thus "second-guess[es] the FDA's decisionmaking").

In the absence of any official agency action finding fraud in the regulatory process and withdrawing Rezulin from the market on account of such fraud, there is no way that respondents can satisfy the Michigan exception without intruding into federal issues of regulatory compliance committed exclusively to FDA. See *id.* at 354 (Stevens, J., concurring in judgment). In other words, because respondents' ability to satisfy Michigan's "fraud-on-the-FDA" turns not on FDA's actual findings, but on a "counterfactual situation" antithetical to the "agency's explicit actions," there is no question that the exception is preempted as applied here. *Id.*; accord U.S. Br. 20.

In arguing otherwise, respondents urge this Court to adopt the Second Circuit's approach. First, respondents (and their *amici*) treat the "presumption against preemption" as somehow protecting these intrusions into FDA's exclusive domain from challenge. As *Buckman* made clear, however, state-law efforts to police the "inherently federal" disclosure duties owed exclusively to the agency deserve no presumption against preemption. 531 U.S. at 347. Moreover, any such presumption would be overcome here, given the depth of interference with FDA functions and the inevitable risk of conflicting findings between FDA and juries.

Next, respondents, as did the court below, imagine "distinctions" between the stand-alone fraud-on-the-FDA claim at issue in *Buckman* and the fraud-on-the-FDA exception to Michigan's product liability defense. But, as exhaustively detailed in our opening brief and the briefs of our *amici*, these distinctions

make no material difference to the preemption analysis. None alters the fundamental point that the proof ultimately required for respondents to establish liability under Michigan law is the same as was found to be impermissible in *Buckman*.

Finally, respondents and their *amici* urge that applying *Buckman* here would undo state-law regulatory compliance defenses generally, negligence *per se* doctrines, and the *Restatement (Third) of Torts*. These claims are wrong. First, the *Restatement* provision on which they rely states plainly that "the matter of federal preemption of state products liability law" is "beyond the scope of this Restatement." *Restatement* § 4, cmt. *e* (1998). In any event, the key distinction between this case and the state-law issues respondents invoke is that the duty that respondents claim was breached is owed exclusively to FDA, not to the public. Whatever rule might apply to state-law efforts to enforce federally created duties owed to the public in other settings, they cannot justify a state law that authorizes juries to inquire into enforcement issues delegated exclusively to FDA when the agency has not itself found that a violation occurred or enforcement is warranted.[1]

In actuality, respondents simply want to relitigate *Buckman*. They argue that the same proof of fraud-on-the-FDA that gave rise to preemption in *Buckman*

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[1] Resolving the constitutionality of Michigan's exception in this case does not implicate whether a preempted conflict may arise between state law and other FDCA-imposed duties such as those involving the adequacy of labeling under federal law. *Compare, e.g.*, Br. Am. Ass'n for Justice 20-34 (wrongly implying that petitioners seek to preempt state tort law). Those issues, however, are raised in *Wyeth* v. *Levine*, __ S. Ct. __, 2008 WL 161474 (Jan. 18, 2008).

should not give rise to preemption in this case, even though it presents the same intrusion into areas of exclusively federal concern and poses the same risks of overburdening the agency. Indeed, respondents' *amici* explicitly argue, in direct contravention of *Buckman*, that fraud-on-the-FDA "is neither inherently nor uniquely a matter of federal concern" and that "the facts that establish state tort liability may also be characterized as 'fraud on the FDA.'" Nat'l Conf. State Leg. Br. 17. This Court should reject this challenge to *Buckman* and reverse the decision of the Second Circuit.

ARGUMENT

THE MICHIGAN EXCEPTION IS PREEMPTED

Nothing in respondents' brief undermines our showing that this case presents a straightforward application of the preemption principles of *Buckman*. Preemption "inevitably" occurs here, as it did in *Buckman*, because the Michigan exception as applied in this case intrudes on an exclusively federal realm involving duties "originat[ing] from, . . . governed by, and terminat[ing] according to federal law." 531 U.S. at 347, 350-51. A fundamental flaw in the analysis of respondents (and their *amici*), like that of the court of appeals below, is to treat this case as a garden-variety state tort action involving duties as between private parties. We address respondents' specific points in turn.

A. There is no presumption against preemption here. In *Buckman*, this Court held that there is no presumption against preemption where a jury is asked to decide whether there has been a material fraud on FDA during the regulatory process. To the contrary, the relationship between a regulated

entity and FDA is "inherently federal in character" and "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* at 347 (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Because the Michigan exception turns on this self-same impermissible inquiry, *Buckman* plainly controls here and there is no presumption against preemption.[2]

In an effort to avoid this analysis, respondents and their *amici* urge that this case be viewed not from the perspective of duties owed to FDA, but as "part of a traditional state tort system aimed at redressing violations of duties of care owed by drug manufacturers to the individuals who use their products." Resp. Br. 17-18; *e.g.*, Nat'l Conf. State Leg. Br. 6 ("Michigan's statute is a classic exercise of state police power"); Kan. Br. 13 (asserting that "this case involves one of the States' most traditional police powers—tort law"). This is wrong, and this fundamental error permeates their arguments. See *infra*. As the United States aptly puts it, "the question here is not whether traditional tort claims are preempted; it is whether the portion of the Michigan statute that requires a finding of fraud on FDA is preempted." U.S. Br. 14. Accordingly, this is not an area of traditional state authority and is not presumptively permissible.

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[2] Respondents' *amici* mistakenly read *Buckman* as applying a presumption that then was "overcome" because "state law inevitably and necessarily conflicts with federal law." Kan. Br. 6. Although we also would meet that standard, *see* Pet. Br. 38 n.14, *Buckman* plainly holds that "no presumption against preemption obtains in this case." 531 U.S. at 348.

B. The fraud-on-the-FDA Michigan exception is materially indistinguishable from the fraud-on-the-FDA claim in *Buckman*. We previously demonstrated why none of the distinctions drawn by the court of appeals between this case and *Buckman* affects the proper preemption analysis. Pet. Br. 41-50. In both cases, the Michigan exception requires the fact-finder to make exactly the same impermissible fraud-on-the-FDA determination.

Echoing the court of appeals, respondents contend that the Michigan exception is not preempted because the complaints here depend on underlying "traditional" common-law tort claims as the ultimate basis for recovery, whereas the claim at issue in *Buckman* was (they assert) limited to allegations that FDA was defrauded. Resp. Br. 21-23; *id.* at 32-33; see Pet. Br. 41-44 (addressing this point). Respondents simply elevate form over substance. *Buckman* hinged on the unavoidable interference that state-law adjudication of questions of fraud-on-the-FDA would pose to the federal scheme. See Resp. Br. 17-18, 21-22. Proof that federal duties to FDA were violated will require as much second-guessing by lay jurors, and be equally harmful to the agency's balance of statutory objectives, whether litigated as a part of the defense or the cause of action. See, *e.g.*, *id.* at 11, 13, 16-17. Federal disclosure requirements were "critical element[s]" of plaintiffs' underlying claim in *Buckman*, 531 U.S. at 353, and are equally "critical" aspects of respondents' case. See Resp. Br. 22; U.S. Br. 11.

Respondents also contend that it matters that the fraud-on-the-FDA inquiry comes into play under Michigan law only if the pharmaceutical defendant first invokes the statutory defense against product liability. See *id.* at 12-13, 22. As put by their *amici*,

federalism principles therefore dictate that "[t]he greater power," which Michigan exercised by providing the statutory defense, "necessarily encompasses the lesser power to impose conditions on the defense"—*i.e.*, to allow a showing of fraud-on-the-FDA. Kan. Br. 7. This is wrong. See Pet. Br. 47-50.

> It long has been settled in this court that the rejection of an unconstitutional condition imposed by a state upon the grant of a privilege, even though the state possess[es] the unqualified power to withhold the grant altogether, does not annul the grant. . . . Broadly stated, the rule is that the right to continue the exercise of a privilege granted by the state cannot be made to depend upon the grantee's submission to a condition prescribed by the state which is hostile to the provisions of the federal Constitution.

United States v. *Chicago, Milwaukee, St. Paul & Pac. R.R.*, 282 U.S. 311, 328-29 (1931) (citations omitted); accord *Frost* v. *Railroad Comm'n*, 271 U.S. 583, 595-99 (1926).

Put another way, the fraud-on-the-FDA exception to the Michigan statute is not a lesser power over which Michigan has exclusive control. Rather, it is a condition that, as applied in this case, requires the jury to make an unconstitutional incursion into a matter of exclusively federal concern. Therefore, it is preempted.

C. The *Restatement* and cases addressing general tort law duties running from the company to the public are inapposite. This case concerns a narrow aspect of a single federal scheme: the disclosure duties regulated entities owe to FDA and the agency's enforcement of those requirements under FDCA. Nonetheless, respondents draw upon

broader and more general state-law tort principles that have no bearing on the preemption inquiry at issue here. Resp. Br. 24-29, 39-40.

1. Contrary to respondents' claims, applying preemption in this case would not interfere with "traditional" state tort law as reflected in the *Restatement* § 4. See Resp. Br. 10, 28-31. That provision is simply a generic statement of state tort law and, by its own terms, does not speak at all to the question of federal preemption, much less preemption under FDA's regulation of federal disclosure requirements. Section 4 of the *Restatement* provides that evidence of a manufacturer's compliance or non-compliance with an applicable "product safety statute or administrative regulation" is relevant in gauging whether a product is defective or not under state law. *Restatement* § 4. Comment *e* to that section further states that, "when the deliberative process that led to the safety standard . . . was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard[,] . . . compliance with regulation is entitled to little or no weight." *Id.* § 4, cmt. *e*. Respondents and their *amici* seize on this language to suggest that applying preemption in our context would radically undermine traditional tort principles permitting compliance inquiries, and not applying preemption would impose no additional burdens or obstacles on FDA. Resp. Br. 15, 18, 30-31.

In truth, this line of argument is simply a *non sequitur* in the context of this case. The first sentence of comment *e*—in language notably omitted from the briefs of respondents and their *amici*—states that "[a]n important distinction must be drawn between the subject addressed in [this section] and the matter of federal preemption of state products

liability law." *Restatement* § 4, cmt. *e*. Section 4 addresses whether and when state tort claims should incorporate product safety standards "*as a matter of state tort law*." *Id.* (emphasis added). It does not address whether and when a state tort claim that incorporates such standards is preempted *as a matter of federal law*. *Id.*[3] As comment *e* points out, preemption must be decided by reference to the "complex set of rules and standards" of federal law, a topic simply "beyond the scope of this Restatement." *Id.* It can hardly be said that a finding of preemption in this case would disturb traditional tort law—when the very provision on which respondents rely recognizes this result. Indeed, none of the cases collected in the *Restatement* annotations remotely involves the issue of fraud on a federal agency.

Put another way, the fraud-on-the-FDA exception at issue here relates not to the duty owed from the manufacturer to the public—the traditional concern of tort law—but instead relates exclusively to the duty owed from the manufacturer to the agency, an area of purely federal concern in the FDCA context presented here. The *Restatement* therefore has no application in this case and lends no support to the validity of the Michigan fraud-on-the-FDA exception. See U.S. Br. 30.

2. Ignoring *Buckman*, respondents also contend that "this Court has long recognized the viability of state-law claims premised on the failure to comply

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[3] Moreover, obviously nothing in the preemption rule we propose or that this Court embraced in *Buckman* remotely interferes with how a state court treats products regulated by *state* agencies. Claims involving fraud on a state agency are not the concern of FDA or federal law. Thus, the *Restatement*'s general rule may apply to many situations where there is no basis for a claim of federal preemption.

with federal regulations" and this precludes preemption here. Resp. Br. 24. None of the cases to which respondents point involves the question of whether the regulated entity committed fraud with respect to FDA (or any other agency) in breach of federal duties created by federal law and owed to the agency alone. See *Buckman*, 531 U.S. at 347-48. For instance, in *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), the Court permitted plaintiffs to pursue injury claims based on the alleged simultaneous violation of federal and state duties governing labeling outside the pharmaceutical context—*i.e.*, warnings which the regulated entity is compelled to provide the public. *Id.* at 442. Breach of duties owed to the public also was the basis for the claims in *Medtronic* v. *Lohr*, 518 U.S. 470 (1996), as well as in *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984).

Here, by contrast, the Michigan statutory exception is not regulating disclosures owed to the *public*. It instead seeks to enforce matters entirely reserved to the agency. See Mich. Comp. Laws § 600.2946(5)(a) (requiring proof that the manufacturer "intentionally withh[eld] from or misrepresent[ed] to [FDA] information concerning the drug that is required to be submitted under the [FDCA] [citing FDCA provisions], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted"). Of note, respondents ignore the pertinent federal statutes, under which "all ... proceedings for the enforcement, or to restrain violations, of [FDCA]" lie with FDA alone, 21 U.S.C. § 337, and the agency has complete discretion to commence or forgo formal enforcement in the face of a violation as it determines appropriate, *id.* § 336. See, *e.g.*, Pet. Br. 10-11, 24-26, 28-29. The cases upon

which respondents rely do not involve such duties, and thus none features the intrusions into the federal scheme at issue here.

Given the comprehensive and exclusive oversight FDA exercises over every aspect of the New Drug Application ("NDA") review process and post-marketing disclosures to the agency, see, *e.g.*, U.S. Br. 1-4, 15-17; Pet. Br. 3-11, injecting state-law into these core FDA functions—and allowing lay juries to second-guess the delicate balances reached by the agency about alleged misrepresentations to the agency and the proper means of enforcement—would "inevitably conflict" with the federal scheme. U.S. Br. 10, 18-22.

3. It is no answer to posit that, because courts have sometimes admitted evidence of compliance with federal safety standards on the issue of product defect, there is no risk of burdening the agency by seeking to litigate the issue of fraud-on-the-agency. Resp. Br. 27, 39-40. There is a significant difference between showing compliance or non-compliance with the terms of an FDA approval, as evidence of product defect under state law, and showing compliance or non-compliance with regulatory requirements governing FDA approval process, and that approval should never have been granted *ab initio*. See U.S. Br. 13 n.2, 18.

Compliance with the terms of an FDA approval may be established through objective evidence. The labeling of an FDA-approved medication either conforms to the FDA-approved language or it does not, and the chemical formulation of the medication is either the same as that approved by FDA or not. These assessments ordinarily do not affect the relationship between the manufacturer and the agency, implicate the testimony of agency officials, or

require speculation by the fact-finder as to how the agency will enforce its statute and regulations. Indeed, here, respondents never questioned the threshold determination that, under the Michigan statute, Rezulin was in compliance with the terms of FDA approval.[4] If a medication is in fact non-compliant with the terms of FDA approval, depending on the circumstances, there may not be a federal law prohibition on a state imposing remedies. See Resp. Br. 24-25 (citing *Lohr*, 518 U.S. at 495). For example, outside the context of this case, a manufacturing flaw claim—*i.e.*, that the drug or device plaintiff used did not conform to the FDA-approved parameters—may survive the pertinent express or implied preemption analysis.

In contrast, the point at issue here—the adequacy of compliance with regulatory requirements governing the FDA approval process, and FDA's

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[4] Though respondents do not dispute the point, one *amicus* argues that to qualify for Michigan's defense against product liability the pharmaceutical company first must establish that it did *not* defraud FDA. *See* AARP Br. 7, 10, 14-15; *contra Taylor* v. *SmithKline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003) (unless an exception "applies[,] . . . a manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller"). Respondents never pressed this point below, nor have they ever suggested that petitioners did not qualify for protection under Mich. Comp. Laws § 600.2946(5). Rather, respondents always have argued that the fraud exception *overcomes* the otherwise applicable statutory defense. *See* Pet. App. 23a-24a; *see also Amicus* Br. of Am. Ass'n Justice 2 ("When a plaintiff does not proffer evidence of misconduct, a court will dismiss a plaintiff's products liability action."). Accordingly, this point has been waived. *See Granfinanciera, S.A.* v. *Nordberg*, 492 U.S. 33, 38-39 (1989); Sup. Ct. R. 15.2.

possible response to a conjectural finding of non-compliance—simply cannot be proved by objective evidence in the absence of official agency action. Any such inquiry would require the jury to make numerous invasive, subjective, expert determinations for which it is institutionally ill-equipped, raising a substantial risk of a state-law finding that FDA was defrauded when the federal government has determined there was no fraud. See U.S. Br. 21-23.[5]

Respondents and their *amici* erroneously suggest that, even without FDA's involvement in litigation, these inquiries are "objective ones" that can be proved through "expert evaluation." AARP Br. 17; see Resp. Br. 40 (arguing that the exception could be satisfied without burdening the agency because there "are so many former FDA medical officers" available to testify). Such proofs are by no means objective. Even most *current* FDA employees are institutionally incapable of answering what the *agency*, as such, would have done; it is fanciful to imagine that *former* employees could properly do so.[6] And, even though

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[5] That federal juries may be called upon to adjudicate criminal guilt *after* the federal government concludes that it has been defrauded and elects to pursue an enforcement action does not, as respondents suggest, cut against preemption. *See* Resp. Br. 26, 39. In that circumstance there is no risk the jury will find fraud-on-the-FDA which the agency itself has not concluded exists. *See generally Buckman*, 531 U.S. at 354 (Stevens, J., concurring in judgment); *accord* U.S. Br. 20. In contrast, absent preemption, private parties would be free to proceed even when the agency itself has not concluded it has been defrauded and would not pursue enforcement. *Cf. Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 727 (2004); *Cook County, Ill.* v. *United States ex rel. Chandler*, 538 U.S. 119, 131 (2003) (recognizing "self-interest" inherent in suits brought by private parties).

[6] *See generally* 21 C.F.R. § 10.85(k) ("A statement or advice given by an FDA employee orally, or given in writing but not

such witnesses could not definitively speak for the agency—and therefore would trespass into FDA's exclusive domain—to the extent such speculation was not properly barred under a *Daubert* challenge, this testimony could be unreliably credited by a lay jury. Indeed, "we may be confronted with the spectacle of one former FDA official testifying what action she would have taken, while another retired FDA official explains that he would have done something quite different." Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation & Tort Law*, 42 St. Louis U. L.J. 163, 177 (1998) ("These counterfactual inquiries are not the stuff of which confidently accurate outcomes are reached in litigation."). All the while, FDA officials who actually make the decisions are fighting to stay out of court so that they may focus their time and attention on serving the public interest by enforcing the FDCA. U.S. Br. 21-22; Pet. Br. 17, 35 & n.13. In the end, there is no appropriate method by which a lay jury could determine whether fraud-on-the-FDA occurred, and how the agency would have remedied such fraud, without answers from the agency itself.

As such, state-law determinations that a manufacturer committed fraud-on-the-FDA, and that a medication would not have been approved absent such fraud, necessarily intrude on FDA's ability to police misconduct consistently with its statutory objectives. See *Buckman*, 531 U.S. at 349; *id.* at 353-54 (Stevens, J., concurring in judgment); see also U.S.

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under this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.").

Br. 18 ("Notwithstanding fraud, FDA may decide that a drug's health benefits counsel against removing it from the market . . . ."). On the other hand, "[i]f the FDA determines both that fraud has occurred and that such fraud requires removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." *Buckman*, 531 U.S. at 354 (Stevens, J., concurring in judgment). In that circumstance, which is not present here, preemption may not be warranted. Indeed, this is the precise position taken by the Sixth Circuit in *Garcia* v. *Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), and the Michigan Court of Appeals in *Duronio* v. *Merck & Co.*, No. 267003, 2006 WL 1628516 (Mich. Ct. App. June 13, 2006) (per curiam), both of which concluded that the Michigan fraud-on-the-FDA exception (i) is preempted when, as here, the agency has not made a finding of fraud but (ii) is not preempted when the agency has found that a manufacturer committed fraud that would have resulted in withdrawal of approval. See *Garcia*, 385 F.3d at 966-67; *Duronio*, 2006 WL 1628516, at *5.

As respondents' acknowledge, Rezulin was not withdrawn on account of fraud-on-the-FDA, nor did FDA find any such fraud. U.S. Br. 5, 21; Resp. Br. 31, 35. Respondents' attempt to invoke the Michigan exception, accordingly, is preempted.

D. The fraud-on-the-FDA exception presents the same intrusion on FDA's domain as did fraud-on-the-FDA claims in *Buckman*. As the United States has made clear, "the conflict is the same as with the stand-alone fraud-on-the-FDA

claims in *Buckman*." U.S. Br. 16-17.[7] Despite respondents' arguments to the contrary, Resp. Br 37-40, permitting state-law proof of fraud-on-the-FDA poses a serious risk of overburdening the agency. As this Court recognized in *Buckman*, if plaintiffs were allowed to bring a claim against manufacturers for failing to disclose information to FDA, manufacturers would have an incentive during the approval process to dump on the agency all possibly relevant information, regardless of whether that information is viewed by the agency as required or material to its deliberations. 531 U.S. at 350-51. This "deluge of information," which the agency "neither wants nor needs," would result in "additional burdens on the FDA[]" and could delay the approval process. *Id.*; PhRMA Br. 30 ("Under the FDCA, responsibility rests with FDA—not the States—to balance the need for material information against the burden of excessive disclosure in the drug approval process."). Identical concerns apply here: if a manufacturer could lose its statutory defense if a jury were to conclude that it failed to disclose some piece of information to the agency, the manufacturer will

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[7] Wrenching a few snippets out of context, respondents urge that any deference to the brief of the United States "is unwarranted because, just last year, the United States advocated a contrary position" in a district court *amicus* brief. Resp. Br. 36 (citing U.S. Br., *Perry* v. *Novartis Pharms.*, No. 05-5350 (E.D. Pa. filed Sept. 21, 2006)). First, the government's position here is entirely consistent with that which it took in *Buckman*. *See* U.S. Br. 16-30, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, No. 98-1768 (U.S. filed Sept. 13, 2000). Second, *Perry* did not touch upon fraud-on-the-FDA, but hinged upon the asserted preemption of failure to warn claims, a subject not implicated here. Finally, read in context, it is plain that the government's point in the *Perry* brief was simply that courts must look to FDA's actions and not speculate about what it might have done divorced from what it actually did do.

have a significant incentive to provide the agency with any and all available information—whether or not that information is required or material in the agency's view.

Respondents contend that the case for interference is somehow less here than in *Buckman* because this case involves the rigorous NDA process, which is not as "speedy" as the abbreviated procedure applicable to the devices at issue in *Buckman*. See Resp. Br. 38-39. Even if true, this does nothing to undo the point. First, a primary mission of FDA is to review NDAs "promptly" and to act on them "in a timely manner," expediting the approval process without sacrificing the quality or rigor of the agency's review. See, *e.g.*, CDER, FDA, *2005 Report to the Nation: Improving Public Health Through Human Drugs* (2005) (mission statement), *available at* http://www.fda.gov/cder/reports/rtn/2005/rtn2005.pdf. Second, the dangers of impeding FDA in the NDA setting may be more acute than they were in the context at issue in *Buckman*, which involved only devices that were "substantially equivalent" to those already on the market. 531 U.S. at 344-47. Here, by contrast, delays in the NDA process would deny patients access to new, life-saving medications. Indeed, first-generation drugs such as Rezulin may be given "priority review" in light of the significant public health interest in promptly bringing such treatments to market. Pet. Br. 13. Given the bulk of a typical NDA, see *id.* at 5 n.1, these federal regulatory goals would be, if anything, more seriously undermined in the NDA context if manufacturers were encouraged to submit yet more reams of information to FDA for only defensive, and not legitimate regulatory, reasons. *Buckman*, 351 U.S. at 350-51.

Thus, the fraud-on-the-agency exception of the Michigan statute, as applied here, poses the same risks of agency interference as the fraud-on-the-FDA claim in *Buckman*. As in *Buckman*, the issue is not whether the agency is already being deluged by unnecessary materials or overwhelmed by subpoenas for staff testimony, but whether state law poses a serious risk that such burdens will arise. 531 U.S. at 350-51; see also U.S. Br. 21-22. If application of the Michigan exception is upheld in this case, in the absence of an official agency finding of non-compliance with regulatory disclosure requirements, any potential defendant that can be sued under that statute will have a strong incentive to create a record of over-disclosure to FDA. That is a burden the federal scheme preempts.

Respondents and their *amici* further contend that competing state-law determinations would not impinge the agency's mission because FDA "rarely if ever" finds itself defrauded. Resp. Br. 31-32. This statement, even if true, does nothing to advance respondents' argument. In the first place, the proper inference is that most pharmaceutical companies do not attempt to defraud FDA, not that the agency is failing to police the FDCA's disclosure requirements. See, *e.g.*, Pet. Br. 4-11, 23-27; U.S. Br. 3-4, 24.

If the implication is that FDA is turning a blind eye to efforts to deceive it, that is demonstrably false and insulting. U.S. Br. 24 n.7. FDA has instituted a number of measures designed to assure data integrity and detect misconduct with respect to the entities it regulates. Where it deems appropriate, the agency has exercised this authority in a number of ways, ranging from issuing warning letters to barring certain investigators from conducting clinical trials to removing products from the market and imposing

fines and other sanctions. See Pet. Br. 9-11. For example, according to the Federal Register, on at least 22 occasions since 1990, FDA has issued formal findings that a sponsor misrepresented information to FDA and the agency withdrew approval of the application on that basis, and FDA's annual "Enforcement Story" lists a number of prosecutions it undertook where it believed the regulated entity had made misrepresentations to the agency.[8] Apart from criminal prosecutions, FDA has implemented an

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[8] *E.g.*, FDA, *The Enforcement Story: Fiscal Year 2005*, at 6-32 (2006) ("Pharmaceutical Firm Found . . . Falsifying Records"), *available at* http://www.fda.gov/ora/about/enf_story/archive/; FDA, *The Enforcement Story: Fiscal Year 2003*, at 6-32 (2004); *United States* v. *Snyder*, 291 F.3d 1291 (11th Cir. 2002) (addressing sentencing issues with respect to company officials found to have made false statements to FDA); *United States* v. *Shah*, 68 F.3d 462 (4th Cir. 1995) (unpublished table decision) (per curiam) (same), *available at* 1995 WL 619955; *United States* v. *Chatterji*, 46 F.3d 1336 (4th Cir. 1995) (same); *United States* v. *Azeem*, 983 F.2d 1057 (4th Cir. 1993) (unpublished table decision) (per curiam) (same), *available at* 1993 WL 5902; *see also* Notice of Withdrawal of Approval of Two New Drug Applications, 66 Fed. Reg. 49030, 49030 (Sept. 25, 2001) (FDA stating withdrawal occurred after it determined the company "submitted untrue statements of material fact in several applications filed with the agency" which "provided sufficient justification to question the reliability" of all application data); 63 Fed. Reg. 30765 (June 5, 1998); 57 Fed. Reg. 49485 (Nov. 2, 1992); 57 Fed. Reg. 32552 (July 22, 1992); 57 Fed. Reg. 30741 (July 10, 1992); 57 Fed. Reg. 19434 (May 6, 1992); 57 Fed. Reg. 14582 (Apr. 21, 1992); 57 Fed. Reg. 11959 (Apr. 8, 1992); 57 Fed. Reg. 6227 (Feb. 21, 1992); 57 Fed. Reg. 3632 (Jan. 30, 1992); 57 Fed. Reg. 3631 (Jan. 30, 1992); 56 Fed. Reg. 63740 (Dec. 5 1991); 56 Fed. Reg. 61431 (Dec. 3, 1991); 56 Fed. Reg. 58060 (Nov. 15, 1991); 56 Fed. Reg. 20433 (May 3, 1991); 56 Fed. Reg. 19117 (Apr. 25, 1991); 56 Fed. Reg. 2528 (Jan. 23, 1991); 55 Fed. Reg. 47542 (Nov. 14, 1990); 55 Fed. Reg. 46245 (Nov. 2, 1990); 55 Fed. Reg. 24934 (June 19, 1990); 55 Fed. Reg. 8995 (Mar. 9, 1990); 55 Fed. Reg. 4236 (Feb. 7, 1990).

"Application Integrity Policy" designed to uncover and address instances of fraud on the agency and untrue statements of material fact in applications submitted for agency review and approval. See Office of Regulatory Affairs, FDA, *Application Integrity Policy* (1998), *available at* http://www.fda.gov/ora/compliance_ref/aip_procedures/AIPprocedures2004_0304.pdf; see also Fraud, Untrue Statements of Materials Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46191 (Sept. 10, 1991).

E. The Second Circuit's decision should be reversed. If the Court determines that the Michigan fraud-on-the-FDA exception is preempted as applied in this case, there is no need to remand for consideration of the severability of the exception or the validity of the remainder of the statute. Remand would be unnecessary with respect to this as-applied challenge because it is already settled that the preempted applications of the fraud-on-the-FDA exception are severable from the remainder of the statute. As the district court below recognized, see Pet. App. 36a, the Sixth Circuit has already held that the fact that the exception is preempted when FDA has not itself found fraud does not require invalidation of other applications or provisions of the statute. *Garcia*, 385 F.3d at 966-67. The Michigan Court of Appeals has concurred in that judgment. *Duronio*, 2006 WL 1628516, at *5.

The Second Circuit acknowledged that its own precedent "mandated deference" and "instructed [it] to defer conclusively to another circuit's judgment . . . when that court of appeals' decision addressed questions of state law from a state within that circuit." Pet. App. 11a (emphasis omitted). This Court has similarly deferred to the judgment of a circuit court concerning the interpretation of state

law within that court's jurisdiction. See Pet. Br. 50 n.18 (collecting cases). There is thus no doubt that, if the Court finds that the exception is preempted as applied in this case (but not when FDA has found through official agency action that fraud has been committed and has withdrawn the drug on that basis, see *Buckman*, 531 U.S. at 354-55 (Stevens, J., concurring in judgment)), the remainder of the statute would remain valid under the Sixth Circuit's interpretation of Michigan law. *Garcia*, 385 F.3d at 966-67; see also *Duronio*, 2006 WL 1628516, at *5.[9] Remand is therefore unnecessary, as the final result—restoration of the district court's judgment—is inexorably ordained. See generally *Thigpen* v. *Roberts*, 468 U.S. 27, 32-33 (1984) (remand unnecessary where issue was argued before the lower courts and could be "decided by a straightforward application of controlling precedent").

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[9] Respondents' argument that petitioners have somehow waived this issue, by failing to include it in the question presented, Resp. Br. 43, is specious. The issue was briefed and argued in the lower courts, *id.* at 42; it was identified again in the petition to this Court, Pet. 18-19; and respondents themselves raised it in their question presented, Resp. Br. i ("Whether federal regulation of drugs impliedly preempts application of the exception to the defense provided under the Michigan statute, *while leaving the defense itself intact.*") (emphasis added).

CONCLUSION

For the foregoing reasons and those presented in petitioners' opening brief, the Second Circuit's decision should be reversed.

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February 8, 2008

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In the Supreme Court of the United States

WARNER-LAMBERT CO., LLC, ET AL., PETITIONERS

v.

KIMBERLY KENT, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTION PRESENTED

Michigan law generally provides that a drug manufacturer is not liable in tort if the federal Food and Drug Administration (FDA) approved the drug, unless the manufacturer "[i]ntentionally withh[eld] from or misrepresent[ed] to the [FDA] information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act * * * and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws Ann. § 600.2946(5). The question is:

Whether federal law preempts state law to the extent that it requires a court to determine whether a drug manufacturer committed fraud on FDA and whether FDA would have denied or withdrawn approval of a drug but for that fraud.

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INTEREST OF THE UNITED STATES

This case presents the question whether state law is preempted to the extent it requires a court to determine, as a prerequisite to the award of tort damages, whether a drug manufacturer committed fraud on the Food and Drug Administration (FDA). Resolution of that question will affect FDA's drug approval process and response to fraud on the agency.

STATEMENT

1. Under the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, a drug manufacturer may not market a new drug unless it has submitted a new drug application to FDA and received the agency's approval. 21 U.S.C. 355(a). An application

must include extensive information about the composition, manufacture, and specification of the drug, any studies of the drug's pharmacological actions and toxicological effects in animals, any studies of the drug's bioavailability and pharmacokinetics in humans, any clinical investigations of the drug, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source." 21 C.F.R. 314.50(d); see 21 U.S.C. 355(b)(1). FDA maintains guidance documents on the format and content of applications to assist applicants in their preparation. 21 C.F.R. 314.50.

The applicant may meet with FDA for the purpose of "reaching agreement" on the design and size of clinical trials intended to form the primary basis of an effectiveness claim, 21 U.S.C. 355(b)(5)(B), and to discuss the presentation of supporting information, 21 C.F.R. 314.50(f)(4). Regulations also provide for a conference approximately 90 days after the application is filed and another conference at the conclusion of FDA's review. 21 C.F.R. 314.102(c) and (d). Those conferences provide an opportunity to resolve disagreements over scientific and medical matters, and meetings may be scheduled at other times to resolve disputes. 21 C.F.R. 314.102(e). There may also be communications by telephone and letter. All conversations, letters, and meetings "shall be appropriately documented" in FDA's files. 21 C.F.R. 10.65(e) and (f), 314.102(a).

FDA will approve a new drug application if it determines that the drug meets statutory standards for safety and effectiveness, manufacturing, and labeling. 21 C.F.R. 314.105(c). The regulations state that, while the same statutory standards apply to all drugs, the

wide range of drugs and the variety of their uses "demand flexibility in applying the standards." *Ibid.* Thus, FDA "is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." *Ibid.*

After a drug has been approved and marketed, the manufacturer must investigate and report to FDA any adverse events associated with use of the drug in humans, 21 C.F.R. 314.80, and must periodically submit any new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug, 21 C.F.R. 314.81. FDA may withdraw approval of a drug if it finds, among other things, that the drug is unsafe or ineffective. 21 U.S.C. 355(e).

Federal law generally prohibits persons from making false or fraudulent statements of material fact to federal agencies. 18 U.S.C. 1001(a). In addition, the FDCA specifically provides for the withdrawal of approval of a drug if FDA finds that "the application contains any untrue statement of material fact," 21 U.S.C. 355(e); 21 C.F.R. 314.150(a)(2)(iv), and includes failing to submit required post-market information to FDA among its enumerated prohibited acts, 21 U.S.C. 331(e). The FDCA was recently amended specifically to prohibit the submission of false or misleading clinical trial information. 21 U.S.C. 331(jj)(3); see 42 U.S.C. 282(j)(5)(D).

The FDCA authorizes FDA to investigate violations of the Act, 21 U.S.C. 372, and to pursue a wide range of sanctions for any fraud it uncovers. The agency may withdraw approval of the drug, 21 U.S.C. 355(e), seek injunctive relief in certain circumstances, 21 U.S.C. 332, seize the drug if it is adulterated or misbranded, 21 U.S.C. 334, or pursue criminal prosecution of the manu-

facturer, 21 U.S.C. 333(a); 18 U.S.C. 1001, 1341. As recently amended, the FDCA also gives FDA authority to seek civil monetary penalties for submission of false or misleading clinical trial information. 21 U.S.C. 333(f)(3)(A).

FDA has instituted an administrative policy regarding appropriate measures for responding to false or misleading statements in drug applications. 56 Fed. Reg. 46,191, 46,199-46,200 (1991); see FDA, *Compliance Policy Guide* § 120.100 (1991) <http://www.fda.gov/ora/compliance_ref/ cpg/cpggenl/cpg120-100.html>. FDA has also established a general process for citizens to petition FDA to take administrative action, 21 C.F.R. 10.30, which may be invoked by any person who believes a manufacturer has defrauded FDA. There is, however, no private right of action to enforce the FDCA. See *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001). The United States has exclusive authority to enforce the Act's provisions, subject only to a limited exception for some actions by States (but not private parties). 21 U.S.C. 337(a).

2. Respondents are Michigan residents who were allegedly injured by Rezulin, a drug marketed by petitioners for the treatment of diabetes. Pet. App. 6a, 30a. FDA approved Rezulin in 1997. Petitioners withdrew it from the market three years later at FDA's request because of adverse side effects in patients taking the drug, see *id.* at 6a-7a, and FDA later withdrew its approval of the drug, 68 Fed. Reg. 1469 (2002).

Respondents filed suit alleging a variety of common-law torts, including breach of express and implied warranties, negligent misrepresentation, defective design, and defective manufacturing. Pet. App. 7a. Michigan law provides:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by [FDA], and the drug and its labeling were in compliance with [FDA's] approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws Ann. § 600.2946(5). That provision does not apply if:

> [T]he defendant at any time before the event that allegedly caused the injury * * * [i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under the [FDCA], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

Ibid. Respondents allege that petitioners knowingly concealed material facts from FDA about the safety and efficacy of Rezulin—including post-approval adverse event reports of liver and heart damage and deaths associated with the drug—which would have prevented approval of Rezulin by FDA or resulted in its earlier removal from the market. Pet. App. 337a, 344a-345a, 353a-354a; J.A. 36, 43. FDA has not made such a determination.

3. The district court dismissed the complaints. Pet. App. 29a-38a. "The question," explained the court, "is whether the plaintiffs, assuming they have adequately pled fraud on the FDA, should be afforded an opportunity to try to prove it." *Id.* at 32a. The court answered that question in the negative because it understood this

Court's decision in *Buckman* to hold that "there can be no recovery on a theory of fraud on the FDA." *Id.* at 33a. The court also deferred to the Sixth Circuit's determination in *Garcia* v. *Wyeth-Ayerst Laboratories*, 385 F.3d 961 (2004), that the fraud-on-the-FDA exception is severable from the remainder of Section 600.2946(5). Pet. App. 33a-34a. Thus, the court concluded, FDA's approval of Rezulin triggered the bar to liability in Section 600.2946(5). *Id.* at 33a-34a, 36a.

4. The court of appeals reversed. Pet. App. 1a-28a. It acknowledged that *Buckman* "held that state 'fraud-on-the-FDA' claims were impliedly preempted by federal law.'" *Id.* at 4a (quoting *Buckman*, 531 U.S. at 348). But the court concluded that "three differences" between the Michigan statute and the state law in *Buckman* compelled a different result in this case. *Id.* at 18a. First, the court held that a presumption against preemption applies in this case, unlike in *Buckman*, because the "object" of the Michigan statute as a whole is to limit traditional tort liability, not to police fraud on the FDA. *Id.* at 18a-19a. Second, the court reasoned that, while the *Buckman* plaintiffs sought to recover based solely on a showing of fraud on the FDA, respondents assert "traditional" common-law tort duties under which liability is not based solely on fraud on the FDA. *Id.* at 20a-22a. Third, the court stated that, under the Michigan statute but not the state law in *Buckman*, fraud on the FDA is a "defense" rather than an "element" of a plaintiff's cause of action. *Id.* at 24a.

SUMMARY OF ARGUMENT

Michigan law is preempted to the extent it requires courts to determine whether a manufacturer defrauded

FDA and whether FDA would have denied or withdrawn approval of a drug but for the fraud.

A. In *Buckman*, this Court held that a state-law fraud-on-the-FDA claim conflicted with federal law and was therefore preempted. The Court explained that the relationship between a federal agency and the entities it regulates is inherently federal, and that state-law fraud-on-the-FDA claims would give applicants an incentive "to submit a deluge of information that the Administration neither needs nor wants, resulting in additional burdens on the FDA's evaluation of an application." 531 U.S. at 351. Because individual drugs differ, the information FDA wants and needs to review a particular drug varies from case to case, based on FDA's exercise of its expert judgment. Moreover, when FDA concludes that it has been defrauded, it has discretion under the FDCA to pursue those remedies that, in its judgment, best fit a violation. Permitting lay juries to second-guess the adequacy of a manufacturer's submission to FDA, and to impose damages (including punitive damages) based on their appraisal of any fraud, would interfere with FDA's exercise of its expert judgment.

B. Justice Stevens concurred in the result in *Buckman* because FDA had not determined "both that fraud ha[d] occurred and that such fraud require[d] the removal of a product from the market." 531 U.S. at 354. That rationale applies here because, as a predicate for imposing liability, the Michigan statute requires that FDA would have denied or withdrawn approval but for the fraud. Speculation by fact-finders about what FDA would have done in hypothetical circumstances invades the province of the agency. Moreover, a legal standard that turned on such speculation would inevitably lead parties to request burdensome and intrusive discovery

from FDA concerning its approval of a drug, and thereby divert the agency from its core public health mission.

C. The court of appeals attempted to distinguish *Buckman* by asserting that it involved a novel claim alleging only fraud on FDA, whereas this case involves a "traditional" tort. Pet. App. 19a. The Michigan statute is not "traditional," however, to the extent that, at bottom, it requires a determination of fraud on a federal agency. That inquiry is problematic whether it occurs as part of a stand-alone tort or in determining the applicability of an exception to a limitation. The state statute's requirement that a plaintiff prove the violation of a traditional tort duty *as well as* fraud on FDA does nothing to diminish the conflicts discussed above. Rather, it means only that those *other* aspects of the state-law claim may not give rise to preemption; it does not reduce the conflict, found in *Buckman*, between federal law and state-law determinations of fraud on FDA.

ARGUMENT

THE MICHIGAN STATUTE IS PREEMPTED UNDER *BUCKMAN* BECAUSE IT REQUIRES A FINDING OF FRAUD ON THE FDA AS A PREREQUISITE TO LIABILITY

Federal law preempts state laws that conflict with federal law, including those state laws that "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). This Court held in *Buckman* that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. The Michigan statute at issue here is preempted because, just like the fraud-on-the-FDA claims in *Buckman*, it makes liability turn on

whether the defendant withheld information from or made misrepresentations to FDA and whether FDA would have approved or withdrawn its approval of the product if accurate information had been submitted.

A. *Buckman* Bars Fraud-On-The-FDA Claims

The plaintiffs in *Buckman* alleged that the defendant had made false representations to FDA in the course of obtaining pre-market clearance under Section 510(k) of the FDCA, 21 U.S.C. 360(k), to market a medical device that was substantially equivalent to a predicate device already on the market. 531 U.S. at 343, 345-346; see *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 478-480, 492-494 (1996) (describing Section 510(k) pre-market clearance process). The plaintiffs sought damages under state tort law, seeking to establish the elements of common-law fraud by showing that false statements were made to FDA, that FDA relied on those statements in approving the product, and that the false statements caused plaintiffs injury because FDA would not have approved the device (and it therefore would not have been on the market and injured them) in the absence of the statements. See *Buckman*, 531 U.S. at 343, 345-346; *In re Orthopedic Bone Screw Prods. Liability Litig.*, 159 F.3d 817, 826-829 (3d Cir. 1998) (*Orthopedic Litig.*) (discussing Restatement (Second) of Torts § 310, at 103 (1965)), rev'd *sub nom. Buckman*, *supra*.

The Court first noted that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied, such as to warrant a presumption against finding federal preemption of a state-law cause of action." *Buckman*, 531 U.S. at 347 (internal quotation marks and citation omitted). "To the contrary, the relationship between a federal agency and the entity it regu-

lates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Ibid.* Accordingly, any presumption against preemption was inapplicable. *Id.* at 347-348.

"Given this analytical framework," the Court held that the fraud-on-the-FDA claims conflicted with federal law and were therefore preempted. *Buckman*, 531 U.S. at 348. That conflict stemmed from the fact that the federal statutory scheme empowers FDA to punish and deter fraud against it, and FDA uses that authority to achieve a "somewhat delicate balance of statutory objectives" that could be skewed by allowing state-law fraud-on-the-FDA claims. *Ibid.* The Court pointed out that the Act and FDA's implementing regulations impose on applicants various requirements to disclose information to FDA, and at the same time give FDA various tools to detect, deter, and punish false statements made during the approval process—including investigatory powers, a citizen complaint process, criminal prosecutions, injunctive relief, and civil penalties. *Id.* at 348-349; see pp. 3-4, *supra* (discussing FDA's enforcement authorities with respect to drugs). The Court also noted that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the Act's provisions. *Id.* at 349 n.4; see 21 U.S.C. 337(a).

The Court explained that the "variety of enforcement options" available exclusively to FDA affords it "flexibility" to make a measured response to suspected fraud against the agency in order to pursue difficult and sometimes competing objectives. *Buckman*, 531 U.S. at 349-350. In the Court's view, state-law fraud-on-the-FDA claims would "inevitably conflict" with FDA's responsi-

bility to "police fraud" consistently with its judgment and objectives. *Id.* at 350. Thus, for example, the prospect of fraud-on-the-FDA claims could deter would-be applicants from seeking approval by FDA of beneficial products because disclosure requirements in the approval process could expose them to liability under state law if the disclosures were found to be incomplete. To allow such claims also would cause applicants to fear that their disclosures to FDA would later be judged insufficient by a state court, which would create an incentive to submit much additional information that FDA neither needs nor wants, thereby burdening FDA and delaying the availability of the product. *Id.* at 350-351.

The Court noted that the fraud-on-the-FDA claims were not based on traditional state tort law principles concerning violation of a duty of care owed by the manufacturer to the plaintiffs, such as an alleged failure to use reasonable care in manufacturing the product. Instead, "the fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements," and "the existence of these federal enactments is a critical element of [plaintiffs'] case." *Buckman*, 531 U.S. at 352-353. The Court concluded that this sort of litigation "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Id.* at 353.

B. Section 600.2946(5)(a) Is Preempted Under *Buckman*

Although the court of appeals pointed to differences between this case and *Buckman*, see Pet. App. 18a-24a, none of those differences is material. Michigan law explicitly makes liability turn on the very same determination that *Buckman* held to be preempted as a predicate to liability under state law. That inquiry exerts the

same "extraneous pull" here as in *Buckman* (531 U.S. at 353) and is equally preempted.[1]

The court of appeals perceived a material difference between the traditional state tort claims at issue here and the fraud-on-the-FDA claims at issue in *Buckman*. Pet. App. 19a-23a. But the claims in *Buckman* were also, at bottom, common-law tort claims, for fraud. See *Orthopedic Litig.*, 159 F.3d at 826-828. What was novel in *Buckman* was not the common-law nature of the underlying tort, but the plaintiffs' suggestion that they could recover in the absence of any duty between the plaintiffs and defendants if they could show fraud on the FDA. This Court found that theory of recovery preempted by federal law because premising liability on proof of fraud on the FDA impermissibly skewed the federal scheme. The decision proceeds on the assumption that, absent preemption, the conduct would violate a state common-law prohibition on fraud. This case, of course, involves not a plaintiff's novel effort to make out a common-law fraud action, but a statute that specifies that liability turns on proving fraud on the FDA.

Under Mich. Comp. Laws Ann. § 600.2946(5), in a product liability action against the manufacturer or seller of a drug, the drug is deemed not to be defective or unreasonably dangerous, and the manufacturer or seller is not liable, "if the drug was approved for safety and efficacy by [FDA], and the drug and its labeling

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[1] The questions presented in the petition ask only whether state law is preempted to the extent it requires a determination of fraud on FDA. See Pet. (i). The petition does not present the question whether or when FDA's approval of a drug impliedly preempts traditional state tort claims, and this brief expresses no view on that question. That question is presented in *Wyeth* v. *Levine*, petition for cert. pending, No. 06-1249 (filed Mar. 12, 2007).

were in compliance with [FDA's] approval at the time the drug left the control of the manufacturer or seller."[2] Section 600.2946(5) then specifies an exception that applies if the defendant, at any time before the event allegedly causing the injury, "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under the [FDCA], and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws. Ann. § 600.2946(5)(a). That provision requires a court entertaining a state-law tort suit to make the same determination that was required and found preempted in *Buckman*. Indeed, the only differences between the inquiry here and in *Buckman* are that here (i) the inquiry is specified by statute, rather than representing an innovative plaintiff's theory of how to prove a common-law claim, and (ii) the inquiry arises not as a stand-alone sufficient basis for recovery, but as a limit on an immunity from liability. The first difference only strengthens the case for preemption, and the second is not material—the inquiry exerts an "extraneous pull" on the federal scheme no matter how it arises.

To be sure, States generally have authority to carve out exceptions from state-law tort duties, as well as limi-

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[2] While that provision specifies both a state-law rule of decision (that the drug is not defective or unreasonably dangerous) and an immunity from liability by reference to actions of FDA under the FDCA, it is not preempted. Just as it is common and often unproblematic for state law to borrow federal law for a standard of care, see, *e.g.*, *Medtronic*, 518 U.S. at 490; a State's decision to borrow federal law as a rule of decision or immunity, *vel non*, does not create a preemption issue (although there could be circumstances where such a state-law immunity provision would frustrate the objects of a federal scheme and therefore be preempted).

tations on those exceptions. But contrary to the court of appeals' belief (see Pet. App. 18a-19a), it does not follow that the substantive terms on which Michigan has chosen to carve out such an exception are automatically entitled to a presumption against preemption. In particular, that presumption "is not triggered when the State regulates in an area where there has been a history of significant federal presence," *United States* v. *Locke*, 529 U.S. 89, 108 (2000), or "where the interests at stake are 'uniquely federal' in nature," *Buckman*, 531 U.S. at 347 (quoting *Boyle* v. *United Techs. Corp.*, 487 U.S. 500, 504-505 (1988)). Because "the relationship between a federal agency and the entity it regulates is inherently federal," *Buckman* held that "no presumption against pre-emption obtain[ed] in th[at] case." *Id.* at 347, 348.

The court of appeals sought to distinguish *Buckman*'s rejection of a presumption against preemption on the ground that Michigan is seeking to "regulat[e] matters of health and safety." Pet. App. 19a (quoting *Buckman*, 531 U.S. at 348). But again, the question here is not whether traditional tort claims are preempted; it is whether the portion of the Michigan statute that requires a finding of fraud on FDA is preempted. Under *Buckman*, the presumption against preemption has no application to that non-traditional feature of the statute, just as it had no application to the non-traditional means of proving fraud at issue in *Buckman*. 531 U.S. at 347; see, *e.g.*, *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199, 1205 (9th Cir. 2002).

The court of appeals may have assumed that the presumption against preemption must apply to a cause of action as a whole, as opposed to one aspect of the case, but there is no basis for that assumption. In *Boyle*, for example, this Court held that the presumption against

preemption did not apply to the question of under what circumstances government contractors have a "defense" to state tort suits. 487 U.S. at 504. There, as here, the state tort as a whole related to health and safety, but the presumption against preemption did not apply to a specific issue implicating uniquely federal interests.

As we demonstrate at greater length below, "[g]iven this analytical framework," *Buckman*, 531 U.S. at 348, Section 600.2946(5)(a) is preempted, just as the fraud-on-the-FDA claims in *Buckman* were preempted.

1. The Michigan statute is preempted because it requires courts and juries, as a predicate to awarding damages, to determine whether an applicant defrauded FDA

a. In *Buckman*, this Court explained that "the relationship between a federal agency and the entity it regulates is inherently federal in character," and "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." 531 U.S. at 347, 348. While *Buckman* involved a medical device, as opposed to a drug, there is no meaningful distinction between drugs and devices in this respect.

As explained above, there is a general prohibition against making false statements to federal agencies. 18 U.S.C. 1001. In addition, the FDCA authorizes FDA to withdraw approval of a drug because of fraud, 21 U.S.C. 355(e), and expressly labels as prohibited conduct the failure to comply with post-approval reporting requirements regarding new safety or efficacy information, 21 U.S.C. 331(e). FDA has authority to investigate suspected fraud by a manufacturer seeking drug approval, 21 U.S.C. 372, and to pursue a wide range of sanctions for any fraud it uncovers, including withdrawal of approval, 21 U.S.C. 355(e), injunctive relief, 21 U.S.C. 332,

seizure, 21 U.S.C. 334, civil monetary penalties, 21 U.S.C. 333(f)(3)(A), and criminal prosecution, 21 U.S.C. 333(a); 18 U.S.C. 1001, 1341. "FDA thus has at its disposal a variety of enforcement options." *Buckman*, 531 U.S. at 349 (footnote omitted).

FDA uses its authority "to punish and deter fraud against the Administration, and * * * to achieve a somewhat delicate balance of statutory objectives," and this "balance * * * can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Buckman*, 531 U.S. at 348. For example, *Buckman* observed that the prospect of fraud-on-the-FDA claims could deter manufacturers from even submitting products for approval because the federal requirements for disclosure to FDA could expose them to state tort liability. *Id.* at 350-351. Also, "fraud-on-the-FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351. Applicants would then have an incentive to submit information that FDA neither wants nor needs, resulting in additional burdens on FDA's evaluation of an application and delays in the approval process and the introduction of the product into the market. *Ibid.*

Of course, Michigan law also requires proof of violations of traditional state-law tort duties owed by a manufacturer to a user of the product that exist independently of the federal regulatory scheme. Issues concerning fraud on FDA—and what FDA would have done if accurate information had been submitted—arise in connection with an immunity from traditional liability that the State has elected to afford. But the conflict is the same as with the stand-alone fraud-on-the-FDA claims in *Buckman*, because in both instances damages may be

awarded only if a court finds that information was withheld or misrepresented to FDA and that FDA would have disapproved the product or withdrawn it sooner if it had received accurate information. See pp. 27-29, *infra*.[3]

b. Section 600.2946(5)(a) also threatens to upset the balance struck by the FDCA and implementing regulations in affording FDA broad discretion to oversee the application process and respond to misrepresentations or omissions of information. The regulations set forth detailed requirements concerning the information manufacturers must submit to the agency, both during the approval process and after a drug has been marketed. See 21 C.F.R. 314.50, 314.80, 314.81; pp. 1-3, *supra*. Those regulations seek to clarify the requirements for manufacturers while relieving the agency of the burden of evaluating unnecessary information.

Because individual drugs differ, the information FDA needs in order to review a particular drug will vary from case to case. Cf. *Merck KGaA* v. *Integra Lifescis. I, Ltd.*, 545 U.S. 193, 207 (2005) (discussing "the uncertainties that exist with respect to * * * what research

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[3] In *Buckman*, the Court focused on the adverse impact that fraud-on-the-FDA claims could have on the Section 510(k) pre-market clearance process for medical devices, which is designed to be comparatively streamlined and speedy. See 531 U.S. at 348-351. This case involves the submission of new drug applications, which entails a far more comprehensive review than under Section 510(k). The preemption question under *Buckman* should be answered as a general matter, however, and should not turn on the procedures that are applicable to the particular product under the FDCA. The basic point of *Buckman*—that FDA is charged with striking a balance between keeping unsafe products off the market and making efficacious products available to patients and doctors that should not be skewed by state law—applies to all of FDA's approval processes under the FDCA.

to include in" a new drug application). FDA "is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. 314.105(c). Because of the complexity of the analysis, an applicant may request a meeting with FDA for the purpose of "reaching agreement" on the design and size of the drug's clinical trials, 21 U.S.C. 355(b)(5)(B), and to discuss the presentation of information, 21 C.F.R. 314.50(f)(4). FDA "usually communicates often with sponsors about scientific, medical, and procedural issues that arise during the review process. Communications may take the form of telephone conversations, letters, faxes or meetings." FDA, *The CDER Handbook* 24 (1998) <http://www.fda.gov/cder/handbook/handbook.pdf>. Permitting lay juries to second-guess the adequacy of a manufacturer's submissions of information to FDA in that ongoing process would interfere with FDA's expert judgment on what information it wants and needs.

Moreover, in situations where FDA concludes that omissions or misrepresentations occurred, the FDCA gives FDA "complete discretion" to pursue those remedies that, in the agency's judgment, best fit a violation and the overall purposes of the Act. *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985). Notwithstanding fraud, FDA may decide that a drug's health benefits counsel against removing it from the market or imposing a severe administrative penalty, and that other sanctions are more appropriate. Awards of damages (including punitive damages) based on state-law determinations of fraud on

the FDA would interfere with FDA's determination of the appropriate remedy.[4]

In these respects, Section 600.2946(a)(5) "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Davidowitz*, 312 U.S. at 67, in conferring authority and discretion on FDA to tailor the application process and choose the appropriate remedies for violations of disclosure requirements. Cf. *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372-374 (2000).

If a State established its own administrative agency to monitor whether regulated entities were withholding or misrepresenting information to FDA, and to impose monetary remedies upon a finding that FDA would have acted differently if accurate information had been submitted, the conflict between that state law and the federal interests would be manifest. As *Buckman* reflects, there likewise is a conflict when monetary remedies are imposed in state-law tort litigation on that basis.

2. The Michigan statute is preempted because it requires courts to determine whether FDA would have denied or withdrawn approval if it had received accurate information

a. There is an additional reason why the Michigan statute is preempted. As the *Buckman* concurrence

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[4] Some state statutes condition the availability of *punitive* damages on a finding that information was withheld from or misrepresented to FDA. See Pet. Br. 11-12 & n.6. Conditioning the availability of punitive damages on that basis would have a particularly acute impact on FDA's oversight of the approval process and selection of remedies for misrepresentation. Cf. *Credit Suisse Sec. (USA) LLC* v. *Billing*, 127 S. Ct. 2383, 2396 (2007) (noting that threat of treble damages would make it impossible for the agency to police fine distinctions between forbidden conduct and closely related conduct that was affirmatively encouraged).

explained, "an essential link in the chain of causation that [a plaintiff] must prove in order to prevail is that, but for [defendant's] fraud, the allegedly defective [product] would not have reached the market." 531 U.S. at 353 (Stevens, J., concurring in the judgment). In the absence of a determination by FDA "both that fraud has occurred and that such fraud requires the removal of a product from the market," plaintiffs could not "establish a necessary element of their claim." *Id.* at 353 n.1, 354. Without such action by FDA, the state law would require a difficult inquiry into "a counterfactual situation" and "second-guessing [of] the FDA's decisionmaking" by state courts and juries. *Id.* at 354.

This Court has long accorded preemptive effect to a federal administrative decision that has neither been rescinded by the agency nor set aside by a federal court in accordance with the procedures for review established by Congress. In *Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 578-579 (1981) (*Arkla*), for example, this Court held that a state contract action was preempted by the Federal Power Commission's (FPC's) approval of a filed rate different from the one provided by contract. Although the state supreme court had determined that the FPC would have approved the higher rate as reasonable had the circumstances of the case been brought to its attention, this Court held that "the Commission alone is empowered to make that judgment, and until it has done so, no rate other than the one on file may be charged." *Id.* at 581. By awarding damages based on a determination of what the FPC *might* have done, the state court "usurped a function that Congress has assigned to a federal regulatory body." *Id.* at 582;

see *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981).[5]

Like the state law in *Buckman*, the Michigan statute requires a determination that "the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws Ann. § 600.2946(5)(a). FDA has never made such a determination. To be sure, three years after FDA approved the application for Rezulin, it asked petitioners to take the drug off the market, and FDA later withdrew its approval for safety-related reasons. See Pet. App. 6a-7a; 68 Fed. Reg. 1469 (2002). FDA did not, however, rely on a finding of fraud in doing so. See 68 Fed. Reg. at 1469. Indeed, when FDA withdraws approval of a drug, it normally does so for reasons other than fraud, including, as with Rezulin, that newly available information revealed that the drug was not as safe or effective as the agency previously thought. See 21 U.S.C. 355(e). Therefore, federal law precludes a state rule—whether as an element of a claim or of a defense—that turns on whether FDA would have denied approval or withdrawn it sooner if it had received accurate information.

b. As the *Buckman* concurrence suggests, and the district court stressed, a contrary result would not only entail intrusive "second-guessing [of] the FDA's decisionmaking," it would also "overburden[] its personnel." 531 U.S. at 354; see Pet. App. 35a-36a; see also U.S. Amicus Br. at 28-30, *Buckman*, *supra*. Parties would

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[5] The *Arkla* Court "save[d] for another day the question whether the filed rate doctrine applies in the face of fraudulent conduct." 453 U.S. at 583 n.13. The *Buckman* concurrence took the next step by recognizing that only the federal agency can determine whether it was defrauded. See 531 U.S. at 353-354 & n.1.

likely seek discovery from FDA concerning whether a manufacturer misrepresented or withheld information that it was required to submit to FDA, as well as discovery concerning the agency's internal deliberations, including agency officials' states of mind and the courses of action they might have taken under various hypothetical scenarios. The United States' position is that employees of the federal government are immune from third-party subpoenas issued in private litigation, that testimony must be sought under an agency's Touhy regulations, see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951), and that an agency's denial of a request for testimony by agency employees is subject to review only in federal court and only under the arbitrary or capricious standard of the Administrative Procedure Act (APA), 5 U.S.C. 706(2)(A). The lower federal courts, however, have taken divergent views on issues concerning third-party subpoenas when issued by a federal court to federal employees. Compare, *e.g.*, *Comsat Corp.* v. *National Sci. Found.*, 190 F.3d 269, 277-278 (4th Cir. 1999) (applying APA standard), with *Exxon Shipping Co.* v. *United States Dep't of Interior*, 34 F.3d 774, 778-780 (9th Cir. 1994) (holding that agency is protected only by court's discretion to limit discovery under Federal Rules of Civil Procedure 26 and 45).

Nor would the undesirable consequences abate if the courts ultimately accepted the government's position on when its officials can be required to testify. Parties would still be free to challenge any refusal to testify under the APA. In one recent products liability class action, *Walson* v. *Merck & Co.*, No. 3:04-cv-00027-GPM-DGW (S.D. Ill.), FDA devoted approximately 1,300 employee hours to producing approximately 40,000 pages of documents in response to a third-party subpoena.

Private litigation such as this would divert FDA's resources and create a substantial potential for distorting its mission.

c. While an FDA decision finding fraud and withdrawing its approval of the product would overcome preemption under the rationale of the *Buckman* concurrence, a rule that made preemption turn on the presence or absence of a decision by FDA could create its own potential for interference with the federal scheme. See 12/4/2000 Oral Arg. Tr. 20-21, 23-25, *Buckman*, *supra* (argument of the United States).[6]

The federal government alone has responsibility to determine the appropriate remedy under the FDCA when it approved a product and later learned of misrepresentations that might have led it not to approve the product. See pp. 18-19, *supra*. The addition of potential damages liability in an uncertain amount under state law to the consequences ensuing from FDA's own remedy under the FDCA would skew FDA's exercise of its discretion under the FDCA. Cf. *Credit Suisse Sec. (USA) LLC* v. *Billing*, 127 S. Ct. 2383, 2396 (2007). In addition, if FDA were the gatekeeper for private tort liability, it could anticipate numerous petitions filed by prospective tort plaintiffs urging the agency to make a finding of fraud. The disposition of such petitions might prove every bit as burdensome for the agency as state-court litigation concerning whether FDA was defrauded. Par-

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[6] We note that, in a preamble to a recent rule, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3936 (2006), FDA provided examples of state-law claims that in its view are preempted under current doctrine by its approval of a drug, including some claims for failure to warn "unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning."

ties would presumably seek extensive information from FDA, pursuant to the agency's Touhy regulations and the Freedom of Information Act, 5 U.S.C. 552, to support or defend against such an assertion. And it could be difficult for FDA to respond to numerous such petitions within the 180-day regulatory timeframe. See 21 C.F.R. 10.30(e)(2).

While FDA takes suggestions of fraudulent representations very seriously, it does not have a process for considering allegations or making explicit findings of fraud in the abstract. Citizen petitions must seek specific types of administrative action, such as withdrawal of a drug's approval, not merely a finding of fraud. See 21 C.F.R. 10.30(b). And even if FDA chose to grant such a petition, it would not necessarily premise the withdrawal on a formal finding of fraud. When FDA suspects fraud, it often reaches a settlement with the applicant in which the applicant pays a fine or takes corrective action (such as changes in labeling) without admitting liability. Thus, FDA does not presently have a system to process routine requests to make findings of fraud in service of private litigation, and any expectation that it do so "would exert an extraneous pull" on FDA, *Buckman*, 531 U.S. at 353, and divert its resources away from its core public health mission.[7]

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[7] When necessary and appropriate, the government has secured formal relief, including criminal convictions, against drug or device manufacturers who defrauded the agency. See, *e.g.*, FDA, *Enforcement Story* (last modified Aug. 7, 2003) <http://www.fda.gov/ora/about/enf_story/archive/2001/ch6/default.htm> (corporate officers sentenced to 15 months of imprisonment for fraudulent submission to FDA); John Henkel, *Investigators' Reports*, FDA Consumer, Nov.-Dec. 1997, at 38 (drug company criminally convicted for, among other things, submitting false statements to FDA in annual reports for approved drugs).

3. FDA's position that the Michigan statute conflicts with federal law is entitled to deference

Any lingering doubt should be resolved by deference to FDA's expert judgment. Congress delegated to FDA authority to administer the process of approving drugs for marketing, monitoring the safety and effectiveness of drugs after they have been marketed, deciding whether to withdraw approval, and determining whether the agency was defrauded and, if so, what remedies to impose. See pp. 1-4, *supra*. As this Court explained in *Medtronic*, FDA's role in administering the drug-approval process makes it "uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" 518 U.S. at 496 (quoting *Davidowitz*, 312 U.S. at 67); see *Geier* v. *American Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2000).

C. The Court Of Appeals' Grounds For Distinguishing This Case From *Buckman* Are Without Merit

The court of appeals sought to distinguish *Buckman* on the ground that it involved a novel claim alleging only fraud on the FDA, whereas, the court of appeals asserted, this case involves a "traditional" tort to which fraud on the FDA is relevant to a defense. Pet. App. 19a-24a. None of the asserted distinctions embedded in the court's description detracts from the fact that the Michigan statute makes liability turn on the very determination that *Buckman* bars.

1. The court of appeals reasoned that respondents' claims are "premised on traditional [tort] duties," not "a newly-concocted duty between a manufacturer and a federal agency." Pet. App. 20a. But there is no material difference between the claims here and in *Buckman*.

Respondents allege claims that *sound* traditional, such as negligence, defective design, and breach of warranty. See *id.* at 7a. But although the fraud-on-the-FDA claim in *Buckman* sounded novel, at bottom, it was a plaintiff's innovative effort to make out a common-law fraud action (against a defendant other than a manufacturer). And, of course, preemption resulted not from the novelty of the claim, but from the fact that liability turned on an inquiry that frustrated the federal scheme. Michigan law is no different.

Under the Michigan statute, "a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable," if, among other things, FDA approved the drug and was not defrauded into doing so. Mich. Comp. Laws Ann. § 600.2946(5). That is not a "traditional" law, and more to the point it calls for the same problematic inquiry that was at issue in *Buckman*. Genuinely traditional tort suits are not preempted under *Buckman* because they do not require a determination that a federal agency was defrauded. But Section 600.2946(5) is preempted precisely because it requires such a finding as a predicate for liability.

Thus, the question is not whether a claim relies on a traditional-*sounding* duty, but whether the particular suit interferes with a federal prerogative. See, *e.g.*, *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 231 (1964) ("Just as a State cannot encroach upon the federal patent laws directly, it cannot, under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws."); see also *American Airlines, Inc.* v. *Wolens*, 513 U.S. 219, 227-228 (1995) (state fraud claims); *Arkla*, 453 U.S. at 573, 580-582 (breach-of-con-

tract action); *Kalo Brick*, 450 U.S. at 323-324, 326-327 (negligence claim).

2. The court of appeals also emphasized that "proof of fraud against the FDA [wa]s *alone sufficient* to impose liability" in *Buckman*, whereas here, a plaintiff must prove more, such as negligence. Pet. App. 20a-21a. The court of appeals also expressed the view that respondents' traditional tort claims "cannot reasonably be characterized as a state's attempt to police fraud against the FDA." *Id.* at 18a. But it is the Michigan statute, not traditional tort claims, that is the proper focus of the preemption inquiry, just as *Buckman* focused on the novel fraud-on-the-FDA theory, rather than a common-law fraud action in the abstract.

In *Buckman*, the Court characterized the claims as "[p]olicing fraud" on the FDA, 531 U.S. at 347, in "inevitabl[e] conflict" with "FDA's responsibility to police fraud" itself, *id.* at 350. The FDCA "leaves no doubt that it is the Federal government rather than private litigants who are authorized to file suit for noncompliance," *id.* at 349 n.4, and allowing private damage actions based solely on violations of the FDCA would conflict with Congress's decision not to provide a private right of action under the FDCA, see *Merrell Dow*, 478 U.S. at 810, 812. While respondents' tort claims, in the abstract, may not be directed at "policing fraud" against FDA, the overlay of Section 600.2946(5)(a) on those tort claims results in the same impermissible intrusion into FDA's oversight of the approval process and its exercise of enforcement discretion as the specific claims in *Buckman*.

Moreover, a plaintiff's need to prove something *in addition to* fraud on the FDA, such as negligence—as well as causation, injury, and damages, which the

Buckman plaintiffs also had to prove—does nothing to eliminate the conflict that results from a state-law requirement that a court make the determination that *Buckman* prohibits as a predicate for liability.[8] Although "[i]n some cases * * * [an] entire body of state law * * * conflicts and is replaced by federal rules," "[i]n others, the conflict is more narrow, and only particular elements of state law are superseded." *Boyle*, 487 U.S. at 508. In *Boyle*, for example, plaintiffs brought a state tort suit for defective design and repair of a Marine helicopter that had crashed, killing the servicemen inside. *Id.* at 502. This Court did not hold that the state tort claims were preempted in their entirety, but instead held that state law was preempted on the specific question of under what circumstances government contractors are immune from state tort liability. *Id.* at 512.

Similarly, in *Arkla*, the state court determined both that the federal commission would have approved a different rate *and* that the plaintiff was entitled to that rate under state contract law. 453 U.S. at 573-575. In that circumstance as in this one, proving an additional element (breach of contract) did not eliminate the conflict. See *Howard* v. *Lyons*, 360 U.S. 593, 597 (1959) (state tort claim subject to specific federal privilege defense). And, of course, in *Buckman*, the Court did not invalidate any aspect of the common law of fraud beyond invalidating the plaintiffs' fraud-on-the-FDA theory.

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[8] Indeed, there may be substantial overlap between the common-law duty and the inquiry into whether FDA would have denied or withdrawn approval but for the fraud. Products liability claims typically require a showing that a product is unreasonably dangerous, see, *e.g.*, *Crews* v. *General Motors Corp.*, 253 N.W.2d 617, 619 (Mich. 1977), and FDA's decision to approve a drug likewise turns in large part on whether the drug is safe, 21 U.S.C. 355(d).

And the problem in *Buckman* was that the plaintiffs' theory required them to prove fraud on the FDA, *not* the happenstance that plaintiffs' theory required them to prove little else.

Consistent with these principles, other courts of appeals have recognized that *Buckman* is not limited to circumstances where liability is premised *solely* on fraud on a federal agency. See, *e.g.*, *Garcia* v. *Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (Section 600.2946(5)(a) preempted); *Kimmel*, 275 F.3d at 1206 (preemption because fraud on federal agency was a "critical element of [plaintiff's] state-law case").[9]

3. The court of appeals "presum[ed]" that, "in most states in the country," evidence of fraud on a regulatory agency is "permitted but not conclusive." Pet. App. 25a. Further presuming that federal law does not preempt the introduction of evidence of fraud on FDA in such circumstances, the court reasoned that "the incentive to supply additional data to FDA under the Michigan law before us is no greater than the incentive that exists whenever evidence of what a company submitted, or failed to submit, to the FDA is admissible and probative of liability." *Ibid.* Thus, the court of appeals concluded, the Michigan statute does not conflict with federal law. *Ibid.*

That analysis is flawed. At the outset, it assumes that juries generally consider evidence of fraud on fed-

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[9] If the exception to immunity is not severable under state law, Section 600.2946(5) is invalid as a whole, and petitioner has no state-law immunity based on FDA's approval of the drug. The United States takes no position on that state-law question because severability analysis is not relevant to the federal preemption question presented here, and the court of appeals did not reach it. Cf. *Garcia*, 385 F.3d at 966-967 (holding that the fraud-on-the-FDA provision is severable from the remainder of Section 600.2946(5)). Cf. p. 12 n.1, *supra*.

eral agencies. It is true that, under the Restatement (Third) of Torts: Products Liability § 4(b) (1998) (Restatement), a jury may consider evidence of "a product's compliance with an applicable product safety statute or administrative regulation" as part of a broader inquiry into whether a product is defective, but that such evidence is entitled to "little or no weight" if "the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product." *Id.* § 4 cmt. e.

In practice, however, relatively few reported cases have involved evidence of fraud on an agency under the Restatement approach (and the court of appeals cited none). And the Restatement emphasizes that "questions of federal preemption are beyond [its] scope." Restatement § 4 cmt. e. At a minimum, there is less incentive to deluge FDA with information in light of the Restatement than in light of the decision below because the question of fraud on the FDA is not dispositive under the Restatement. The conflict with federal law also is not as sharp because the Restatement approach does not require a finding of fraud or that the federal agency would have disapproved the product in the absence of fraud. But regardless of how preemption and related issues might play out in *that* context, there is clearly preemption where, as here and in *Buckman*, findings that FDA was defrauded and that FDA would have disapproved or withdrawn its approval of a product in the absence of fraud are legally mandated predicates for recovery.

4. The court of appeals also found it relevant that fraud on the FDA is not an "element" of respondents' claims, but instead rebuts a defendant's reliance on the "affirmative defense" of FDA approval. Pet. App. 23a-24a. That distinction, too, is immaterial.

At the outset, it is not clear that fraud on the FDA is only relevant to an affirmative defense. Section 600.2946(5)(a) states that "a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable," if, among other things, FDA approved the drug and was not misled. The defective or unreasonably dangerous nature of a product is ordinarily an element of a products liability claim. See, *e.g.*, *Crews* v. *General Motors Corp.*, 253 N.W.2d 617, 619 (Mich. 1977). And respondents' complaints affirmatively allege fraud on the FDA. Pet. App. 337a, 344a, 354a; J.A. 33, 36, 43. The court of appeals relied on the Michigan Supreme Court's description of the statute as providing an "absolute *defense*." Pet. App. 23a (quoting *Taylor* v. *Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (2003)). But *Taylor* did not fully consider whether Section 600.2946(5) is relevant to a plaintiff's prima facie case or an affirmative defense—or whether the plaintiff bears the burden of proof on the exception once the defendant invokes the general rule of non-liability—because the issue there was whether the statute is constitutional. See *Taylor*, 658 N.W.2d at 137.

In any event, there is no reason why a state-law label would matter for conflict preemption purposes. All that matters is that the state statute requires a determination of fraud on FDA as a predicate to liability, and therefore conflicts with federal law under *Buckman*. Whatever label Michigan might place on the inquiry, "courts would have to engage in the [same] intrusive

inquiry which * * * is forbidden." *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.), cert. denied, 516 U.S. 815 (1995). Any "attempt to reexamine the FDA's approval under state law standards, however pleaded, is pre-empted." *Ibid.*

The court of appeals appears to have been influenced by the fact that Section 600.2946(5), as a whole, benefits drug manufacturers by providing a defense to an otherwise traditional tort claim. See Pet. App. 18a-19a. While that question may have some relevance to the state-law severability question that is not before the Court, see p. 29 n.9, *supra*, it does not affect the reality that liability ultimately turns on the fraud-on-the-FDA inquiry and that inquiry is preempted under *Buckman*. Depending on the answer to the severability question, the finding of preemption may ultimately help the plaintiffs or the defendants. But the preemption inquiry does not turn on whether the law is "pro-defendant." In *Mackey* v. *Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 830 (1988), the Court held that the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001 *et seq.*, preempted a state statute that singled out federal benefit plans for *favorable* treatment because "[l]egislative 'good intentions' do not save a state law" that intrudes on the federal sphere. Preemption does not exist to help particular parties; it exists to protect the federal sphere from interference by the States.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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IN THE
Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

BRIEF OF AMICUS CURIAE AARP IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE[1]

AARP is a nonpartisan, nonprofit organization with nearly forty million members, including members in each of the fifty states and the District of Columbia. AARP works to foster the health and economic security of individuals as they age. To that end, AARP supports efforts at the state and national level to ensure access to safe and effective health products. AARP is greatly concerned about the safety of prescription drugs because older people disproportionately use them. AARP supports laws and public policies designed to protect its members' rights and to preserve the availability of legal redress when AARP members are harmed in the marketplace through no fault of their own.

AARP has a significant interest in this case. The issue before the Court directly affects the ability of AARP's members in Michigan to seek redress when injured by dangerous pharmaceutical products that were approved by the Food and Drug Administration (FDA), or remained on the market, notwithstanding the fact that the manufacturer intentionally violated FDA requirements.

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[1] Pursuant to Rule 37.6 of the Rules of the Supreme Court of the United States, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

More broadly, the Court's resolution of the preemption question in this case may have repercussions in any case in which plaintiffs seek to make out common law tort or negligence *per se* claims by demonstrating that a drug's manufacturer intentionally violated federal statutory or regulatory requirements. Petitioners and their *amici* seek to forbid tort plaintiffs from relying on evidence that drug companies intentionally failed to submit required data, or deliberately misrepresented safety data, to the FDA. They contend that permitting plaintiffs to rely on such a showing might undermine FDA enforcement efforts.

History, of course, refutes that argument. State law tort claims founded on violations of federal law have been standard fare for decades, with no evidence of any impairment to the FDA. Limiting the right to recover for injuries caused by the intentional misconduct of drug companies, by barring plaintiffs from showing that their injuries resulted from the companies' deliberate failure to comply with federal standards, would deprive AARP members of the remedy historically guaranteed to them by common law. For these reasons, AARP has a strong interest in this case and it can offer a different perspective on the issues before the Court than those presented by the parties.

STATEMENT

1. Background

This case was dismissed by the district court on petitioners' Rule 12(c) motion for judgment on the pleadings. This statement is based on publicly available evidence that the plaintiffs would likely offer

to the trier of fact on remand. *See generally Desiano v. Warner-Lambert,* 326 F.3d 339, 341-43 (2d Cir. 2003); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 63-64 & n.6 (S.D.N.Y. 2002). Rezulin is a prescription drug that was approved by the FDA in January 1997 for the treatment of Type-2 diabetes, and then marketed and sold by Warner-Lambert between March 1997 and March 2000. Rezulin's brief, three-year tenure on the market was marred by increasingly dire concerns over Rezulin's liver toxicity. Indeed, five times during those three years the FDA pushed Warner-Lambert to make significant modifications to Rezulin's label and prescribing information to require increasingly rigorous monitoring of patients' liver functions, reflecting the agency's growing concern about the dangers posed by the drug. *See id.; see also* Willman, *The Rise and Fall of the Killer Drug Rezulin*, L.A. TIMES, June 4, 2000, at A1 (hereinafter "Willman, *The Rise and Fall*").[2] Finally, in March 2000, at the FDA's request, Warner-Lambert withdrew Rezulin from the market. *See* Press Release, FDA, *Rezulin to Be Withdrawn from the Market* (March 21, 2000), *available at* http://www.fda.gov/bbs/topics/NEWS/NEW00721.html.

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[2] The FDA has only recently been given authority to mandate labeling changes. *See* Pub. L. 110-85, § 901 121 Stat. 823 (Sept. 27, 2007) (*to be codified at* 21 U.S.C. § 355(o)(4)). During the time Rezulin was on the market, the FDA had to negotiate with drug companies over the contents of labeling and drug warnings. *See* U.S. Gov't Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* 10 (2006) (GAO-06-402) (hereinafter "GAO Drug Safety Report").

There is also evidence suggesting that Warner-Lambert intentionally withheld information from, and misrepresented data to, the FDA in an effort to downplay evidence of Rezulin's liver toxicity. *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. at 63-64 & n.6 Warner-Lambert did so initially to obtain FDA approval for Rezulin and thereafter to keep Rezulin on the market. *See id.; see also* Whitcomb & Watkins, *Hepatic Dysfunction Associated with Troglitazone*, 338 New Eng. J. Med. 916 (1998). Warner-Lambert also resisted, for more than six months, the FDA's request that it cease marketing Rezulin as a stand-alone drug. *See* Willman, *"Fast-Track" Drug to Treat Diabetes Tied to 33 Deaths*, L.A. Times, Dec. 7. 1998, at 1. Throughout the three year period Rezulin was on the market, Warner-Lambert continually touted Rezulin's safety and denied the mounting evidence of its risks. *Desiano*, 326 F.3d at 342-43. Rezulin was responsible for ninety-four reported cases of liver failure, including sixty-six deaths.[3] Willman, *Hidden Risks, Legal Truths: Warner-Lambert Won Approval For Rezulin After Masking The Scope Of Liver Injuries In Clinical Studies*, L.A. TIMES, June 30, 2002, at 1.

2. Proceedings Below

The named plaintiff in this case, Kimberly Kent, is a resident of Michigan and the daughter of Virginia Kent, who died at age 62 from acute liver failure after

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[3] This figure is based on cases voluntarily reported to the FDA. Experts estimate that the actual number of liver failures and deaths may be as high as ten times this amount. Willman, *The Rise and Fall*; Nick Anderson, *Rezulin's Swift Approval, Slow Removal Raise Issues*, L.A. Times, March 23, 2000, at A1.

taking Rezulin. Individually, and as a class representative, Ms. Kent sued Warner-Lambert, alleging common law claims, including breach of implied and expressed warranties, negligence, negligent misrepresentation, negligence *per se*, fraud, defective design, defective manufacturing, and loss of consortium. *Kent* was filed in federal court in Michigan and was transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the Southern District of New York. The District Court granted Warner-Lambert's motion for a judgment on the pleadings and dismissed the claims of Ms. Kent and other plaintiffs who had alleged that they or their loved ones sustained serious liver damage as a result of Rezulin.

The Second Circuit reversed. *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006). The court held that, under Michigan law, Ms. Kent's claims "depend primarily on traditional and preexisting tort sources, not at all on a 'fraud-on-the-FDA' cause of action created by state law, and only incidentally on evidence of such fraud." *Id.* at 98. The court decided that this distinguished the case from *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). *Id.*

3. The Michigan Statute

Prior to 1995, Michigan law provided that, in a product liability action brought against a drug company, "compliance with governmental and industrial standards is admissible as evidence but is not [a] conclusive" defense. *Owens v. Allis-Chalmers Corp.*, 326 N.W.2d 372, 376 (Mich. 1982). In 1995, the Michigan legislature passed an amendment to the law

to provide a company a complete affirmative defense when, but only when, the company proves that both the drug and its labeling comply with FDA requirements. *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 134 (Mich. 2003).

The relevant section of the statute provides:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws § 600.2946(5). The statute further provides that, even if a company makes the threshold showing for a regulatory compliance defense, the defense is nonetheless forfeited if:

> [T]he defendant at any time before the event that allegedly caused the injury (a) [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the food, drug, and cosmetic act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted. . . .[or] . . . (b) [it] [m]akes an illegal payment to an official or employee of the United States [FDA]

> for the purpose of securing or maintaining approval of the drug.

Id.

Petitioners contend that they have no affirmative duty to prove that Rezulin and its labeling were, in fact, in compliance with FDA requirements, beyond simply producing an FDA approval letter and submitting a declaration from a company official claiming that the company complied with applicable FDA requirements. Petitioners further claim that subsection (a), which denies companies a regulatory compliance defense if they have not been forthcoming with the FDA, is preempted and must be severed from the remainder of the statute because it requires proof of fraud on the FDA. As a result, petitioners ask this Court to rewrite Michigan law to provide them and other drug companies complete immunity from tort liability even if they intentionally disregard FDA requirements by withholding or misrepresenting health and safety data, even if the data would have been material to the FDA's approval, and, if one takes petitioners' argument to its logical conclusion, even if they make illegal payments to FDA officials.

4. The Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug and Cosmetic Act (FDCA) requires companies seeking to obtain the FDA's approval to market a new drug to submit a "new drug application" containing all information bearing on the drug's safety and effectiveness, including the results of animal testing and pharmacological studies, as well as full reports of the clinical trials performed on human

subjects. 21 U.S.C. § 355(a)-(b); 21 C.F.R. Part 314. The FDA "determine[s] the kind and quantity of [additional] data an applicant must provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105(c). The FDA may approve a new drug only if it determines that the drug is "safe and effective" for its intended uses and that its labeling is not "false or misleading." 21 U.S.C. §§ 321(p)(1)-(2), 355(b)-(d).[4]

Approval does not end a company's reporting obligations; on an ongoing basis, companies must provide the FDA with records "relating to clinical experience" and adverse reactions, file comprehensive annual reports, and permit the FDA to review their business records. 21 U.S.C. §§ 355(k), 374; 21 C.F.R. §§ 314.80, 314.81. It is unlawful to withhold or intentionally misrepresent health and safety information submitted to the FDA. *See, e.g.*, 18 U.S.C. § 1001; 21 U.S.C. §§ 307b(a)(1), (a)(4); 355(b), (k). And the FDCA is quite clear that the Secretary "shall" deny or withdraw approval of a drug if "the application contains any untrue statement of material fact." 21 U.S.C. § 355(e)(5); *see also id.* § 355(j)(3)(K).

INTRODUCTION AND SUMMARY OF ARGUMENT

AARP files this brief as *amicus curiae* to make three points that may not stand out in respondents' more comprehensive treatment of the issues:

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[4] *See also* http://www.fda.gov/cder/regulatory/applications/default.htm (describing the drug approval process).

First, the claims of Ms. Kent and the other respondents are garden-variety common law tort claims that have been raised against drug companies for decades. *See generally Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804 (1986); *see also* David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461 (2008). At no point has this or any other appellate court held that federal law preempts traditional common law claims involving FDA-approved drugs.[5] Given the absence of an express preemption provision in the FDCA, and Congress' longstanding awareness of products liability litigation against drug companies, this is unsurprising. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 161-67 (1989). The fact that Michigan provides a regulatory compliance defense that is stronger than most other states' does not change the nature of the plaintiffs' claim in this case. For this reason, the Court's ruling in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), setting aside a novel "fraud-on-the-FDA" claim on conflict preemption grounds, has no bearing here.

Second, to shoehorn this case into *Buckman*'s mold, petitioners and their *amici* rewrite Michigan law to reverse both the order and the burden of proof established by the Michigan statute. The point of the

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[5] The Court has been asked to grant review in *Wyeth v. Levine*, *petition for cert. pending*, No. 06-1249 (filed Mar. 12, 2007), to decide whether state tort failure-to-warn claims are preempted by virtue of FDA-approved labeling, where the drug company can show that its drug was labeled in compliance with FDA standards.

Michigan law is to give companies that play by the rules the benefit of a complete regulatory compliance defense that is generally unavailable under common law. But the statute does not seek to extend liability protection to companies that play fast and loose with FDA requirements. For that reason, the statute requires a company claiming a regulatory compliance defense to show that it "*properly* obtained FDA approval." *Taylor*, 658 N.W.2d at 134 (emphasis added). The statute places the initial burden on the company to *prove*, not simply allege, that the drug and its label in fact "*were in compliance with*" FDA approval requirements when the drug left the company's hands. Mich. Comp. Laws § 600.2946(5) (emphasis added). Companies that intentionally withhold or deliberately misrepresent vital safety information required by the FDA cannot establish compliance with FDA requirements, *see* 21 U.S.C. §§ 307b(a)(1), (a)(4), 355(b), (e)(5), (j)(3)(K), (k), and therefore cannot make the threshold showing required by Michigan law.

To be sure, the Michigan statute goes on to provide that, even if a company satisfies the threshold requirement of showing regulatory compliance, the defense is nonetheless unavailable if the company intentionally withholds or misrepresents data to the FDA and the drug would not have been approved, or the FDA would have withdrawn approval, if accurate information were submitted. Mich. Comp. Laws § 600.2946(5)(a). In other words, the defense is unavailable if the company makes a material misrepresentation to, or withholds material information from, the FDA. That approach appears to mirror the one established in the FDCA, which authorizes civil

penalties for such conduct and directs the FDA to deny or withdraw its approval of a drug where the sponsor has made an "untrue statement of material fact." *See* 21 U.S.C. § 355(e)(5); *see also id.* § 355(j)(3)(K). As explained below, subsection (a) is not preempted under *Buckman* because courts can determine a company's liability without the FDA's participation and because a determination that a company violated subsection (a) would not implicate, let alone interfere with, the FDA's enforcement or regulatory prerogatives.

Third, if the Court disagrees and finds subsection (a) preempted, then it must remand this case for resolution of the thorny severability question that such a ruling would pose. Given the clear goal of the Michigan legislature to provide broader but not unlimited liability protection to drug companies, simply severing subsection (a) of Mich. Comp. Laws § 600.2946(5) from the remainder of the statute would turn the Michigan law on its head. Such a ruling would confer blanket immunity on a drug company even though it intentionally withheld or distorted material information to the FDA, even though truthful information would have led the FDA to withdraw the drug's approval, and presumably even if the company made illegal payments to FDA officials. Such a result cannot be squared with the evident purpose of the Michigan legislature to give liability protection only to those companies that "properly obtained FDA approval." *Taylor*, 658 N.W.2d at 134. Therefore, if this Court holds that any portion of Mich. Comp. Law § 600.2956(5)(a) is preempted, the case should be remanded to the Second Circuit with directions to undertake further proceedings to address severability.

ARGUMENT

I. *Buckman* Does Not Preempt The Traditional Common Law Claims At Issue Here.

In *Buckman*, this Court addressed a narrow legal question based on an unusual set of circumstances. The defendant, Buckman, was a consultant hired by AcroMed to help it obtain FDA approval for orthopedic bone screws. *Buckman*, 531 U.S. at 343. The plaintiffs were individuals claiming injuries caused by the bone screws. *Id.* They successfully asserted state tort claims against AcroMed. However, the plaintiffs had no traditional theory of liability against Buckman because, as a consultant, Buckman had no contact with patients or doctors and was not involved in the manufacture or sale of the screws.

Undeterred, the plaintiffs advanced a novel "fraud-on-the-FDA claim," which premised liability on the theory that Buckman had defrauded the FDA. The Court rejected this theory, holding that such claims "conflict with, and are therefore impliedly preempted by," the FDCA. *Id.* at 347. The Court observed that the plaintiffs' claim did not "rely[] on traditional state tort law which had predated the federal enactments in question," that their "claim[] exist[ed] solely by virtue of the FDCA disclosure requirements," and that "the existence of these federal enactments [was] a critical element in their case." *Id.* at 353.

In contrast, the claims at issue here—common law tort claims—are premised on traditional tort duties product manufacturers owe to Michigan consumers. *See Desiano*, 467 F.3d at 88, 94-95. None of the claims

rely on the existence of FDCA disclosure requirements or other federal laws. And nothing in *Buckman* suggests that traditional common law claims are preempted. To the contrary, the *Buckman* Court found that the ordinary presumption against preemption did not apply in that case because the claim for relief at issue did not arise under common law, but in fact derived from the FDCA itself. *Buckman*, 531 U.S. at 347. The Court ruled that policing fraud against the FDA was a job for the FDA to handle. *Id.* at 348. But that logic has no bearing in this case, which concerns the common law duties that drug companies owe consumers. The job of compensating people injured through the fault of others has historically been the exclusive province of state tort law. The *Kent* respondents have invoked common law claims to remedy wrongdoing by Warner-Lambert against themselves and their loved ones who were killed or seriously injured by Rezulin. Because these claim arise under conventional state tort law, *Buckman* is not controlling. *See id.*; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (invoking presumption against preemption to preserve common law claims).

II. Subsection (a) Is Not Preempted.

Petitioners concentrate their fire on subsection (a) of Mich. Comp. Laws § 600.2946(5), as if it is the keystone of the statute. But that reading of Michigan law is plainly wrong. The statute begins by offering drug companies expanded protection from tort liability where the company can show that it dutifully complied with FDA requirements. As the Michigan Supreme Court has observed, "the [Michigan] Legislature has determined that a drug manufacturer or seller that has

properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Taylor*, 658 N.W.2d at 134 (emphasis added).

Thus, to make out a regulatory compliance defense under Michigan law, the initial burden falls on Warner-Lambert to prove not just that it obtained FDA approval, but that it *"properly"* obtained FDA approval and sold Rezulin "in compliance with FDA approval" requirements. *Id.* (emphasis added); Mich. Comp. Laws § 600.2946(5). The statute therefore requires something more from a drug company than simply producing an FDA approval letter and a self-serving declaration from a company official asserting that the company has fully complied with FDA requirements. The statute, in the words of *Taylor*, requires the company to show that it has "properly" obtained FDA approval. To make that showing, the company would be required either to demonstrate that it did not withhold or distort information that may have been material to the FDA's approval decision, or, at the very least, to refute plaintiffs' evidence that the company engaged in wrongdoing. Indeed, that is the ordinary allocation of the burden of proof in cases in which drug companies seek to take advantage of a regulatory compliance defense. *See* Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049 (2000).

Under this conventional reading of Michigan law, evidence that Warner-Lambert intentionally withheld or misrepresented required information is relevant to, and would refute, Warner-Lambert's claim of compliance. *See, e.g.*, 21 U.S.C. § 355(b), (e)(5), (j)(3)(K), (k). For this reason, the linchpin of the statute is the burden it places on drug companies to establish all of

the elements of a traditional regulatory compliance defense; only if a company does so is it eligible for the complete defense offered by Michigan law. Petitioners and their *amici* would have the Court simply skip over this crucial step of the analysis, but this step is plainly compelled by Michigan law.[6]

Petitioners ask the Court to bypass the threshold test under Michigan law and go immediately to the second step in the statute, which functions as a failsafe. This part of the statute disqualifies a company for a regulatory compliance defense if the company (a) withheld information from, or misrepresented information to, the FDA that was material to the FDA's approval process, or (b) made illegal payments to FDA officials. Mich. Comp. Laws § 600.2946(5)(a)&(b).[7] Petitioners claim that sub-

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[6] This reading of the statute, which is compelled by *Taylor*, suggests that consideration of the issue presented in this case is premature. Given the district court's dismissal of the case on Rule 12(c) grounds, and the Second Circuit's reversal of that ruling, there has been no opportunity for the plaintiffs to develop facts relevant to whether Warner-Lambert intentionally withheld records from the FDA that it was required to submit or misrepresented facts to the agency. If there is evidence that Warner-Lambert used improper means to obtain FDA approval, or to keep Rezulin on the market, then the company's effort to take advantage of Michigan's complete regulatory compliance defense would fail at the threshold, *see Taylor*, 658 N.W.2d at 134, and the preemption question presented in this case would not arise. For that reason, the Court might want to consider whether the writ was improvidently granted or whether the case should be remanded for a more thorough evaluation of this threshold question under a proper reading of Michigan law.

[7] While petitioners' reluctance to address subsection (b) (continued...)

section (a) amounts to a requirement that the plaintiff prove "fraud-on-the-FDA" to make out their common law claims, and thus their claims are preempted under *Buckman*.

This argument is flawed. *Buckman*'s core holding is that the FDA must be given breathing room to take measures to safeguard itself against fraud. Judicial intervention might interfere with that interest. But subsection (a) does not implicate that concern. Enforcement of subsection (a) neither requires the FDA's participation nor interferes with FDA enforcement or regulatory prerogatives.

Nothing in the Michigan statute calls on courts to second-guess FDA regulatory or enforcement decisions. There is a long history of products liability litigation against the drug industry based on claims that a company made misrepresentations to or withheld material information from the FDA.[8] That litigation

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[7](...continued)
may be understandable, the provision cannot simply be ignored. Under the logic of petitioners' argument, a claim under subsection (b) would be preempted as well, since the FDA can be expected to police instances of bribery as vigorously as instances of fraud. But such a conclusion would require the wholesale revision of Michigan law, which plainly sought to deny liability protection to companies that bribe FDA officials.

[8] *See, e.g., Stanton v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 559-62 (3d Cir. 1983) (failure to submit adverse reaction reports); *Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 733 (2d Cir. 1979) (failure to adequately warn of drug's risk); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 138 (3d Cir. 1973) (failure to seek FDA approval for new use of drug); *Toole v. Richardson-*
(continued...)

has proceeded in both federal and state courts for decades with no claim that it has interfered with the FDA's ability to enforce the law. There is no reason why now, all of a sudden, that litigation threatens the FDA's ability to do its job.

The structure of the Michigan statute serves as a safeguard against interference with the FDA. The statute places the initial burden on the company to prove its regulatory compliance defense. The evidence needed to substantiate the company's claim would come from the company's own files—not from the FDA. And in cases like this one, where the heart of the plaintiffs' claim is that the petitioners withheld information from and misrepresented data to the FDA, those facts are objective ones that can be established, as they are every day in ordinary tort litigation, on the bases of the company's records and expert evaluation of them, without the FDA's involvement.[9] *See supra* note 8.

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[8](...continued)
Merrell, Inc., 60 Cal. Rptr. 398 (Cal. App. 1967) (submission of false and misleading information to the FDA); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (sale of misbranded medical device); *see also Bristol-Myers v. Gonzales*, 561 S.W.2d 801 (Tex. 1978) (failure to adequately warn of drug's risk, where company knew of risk before it alerted the FDA); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973) (failure to adequately warn of drug's risk); *Parke-Davis and Co. v. Stromsodt*, 411 F.2d 1390, 1402 (8th Cir. 1969) (failure to adequately warn of drug's risk and inadequate testing of drug).

[9] The FDA has long and generally successfully resisted efforts by parties to private litigation to force the agency to participate. *See* 21 C.F.R. § 20.1; *see also In re David A. Kessler*, 100 F.3d 1015, 1016 (D.C. Cir. 1996).

Nor is there force to petitioners' argument that litigating over a subsection (a) claim would somehow enmesh the FDA in private tort litigation. Petitioners argue that the language in subsection (a) requires a showing that the FDA found fraud or would have denied or withdrawn approval if the information had been accurately submitted. But that overstates the burden imposed by the Michigan statute, which does not use the word fraud. In fact, the language of the Michigan statute, as a practical matter, mirrors federal law. Under the FDCA, the FDA "shall" deny or withdraw approval of a drug if "the application contains any untrue statement of material fact" 21 U.S.C. § 355(e)(5); *see also* § 355(j)(3)(K). Under Michigan law, courts shall deny companies a regulatory compliance defense if they have omitted or distorted information that would affect an FDA approval decision. Thus, the question under Michigan law distills to whether the company's omission or distortion of information was "material." Questions of materiality are generally the province of courts, and courts routinely make materiality decisions notwithstanding the fact that they may also be made by agencies that have concurrent enforcement authority.[10] There is no reason why Michigan courts,

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[10] *See, e.g., Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71 (2006) (determination of materiality in securities case made by courts, not just the Securities and Exchange Commission); *Burlington Northern & Santa Fe Ry. v. White*, 126 S. Ct. 2405 (2006) (determination of materiality of adverse employment action taken allegedly in retaliation for exercising protected rights made by courts and not just the Equal Employment Opportunity Commission); *see also Neder v. United States*, 527 U.S. 1 (1999) (question of materiality for the courts

(continued...)

or federal courts applying Michigan law, cannot reach decisions about materiality without the FDA's involvement.

It also bears emphasis that courts will need to reach the questions posed by Mich. Comp. Laws § 600.2946(5)(a), (b) only in the rarest cases. As noted above, the statute places an initial, affirmative duty on the company to prove all elements of regulatory compliance, and evidence of material information withheld, or material information misrepresented, would negate such a defense. Subsections (a) and (b) deny a defense to companies that might satisfy the basic requirements for the regulatory compliance defense but have nonetheless engaged in serious and disqualifying misconduct. But the inquiry called for under subsection (a) is no different than the inquiry courts will have to make in assessing the evidence produced to support or rebut the company's regulatory compliance defense: just as material omissions and misstatements would refute a company's claim to a regulatory compliance defense, so too would they disqualify a company under subsection (a). There is no reason why evidence the company could use *to establish* the regulatory compliance defense it seeks under Mich. Comp. Laws § 600.2946(5) is somehow tainted if used by the plaintiff *to disqualify* the company from the defense under subsection (a). Petitioners offer no explanation as to why their use of

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[10](...continued)
under tax fraud statute); *see also* Fed. R. Civ. P. 56 (courts determine whether a fact in genuine dispute is "material" in deciding summary judgment motions). *See generally KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007)).

evidence to support a regulatory compliance defense raises no preemption concerns while respondents' use of similar evidence to rebut the company's defense is preempted.

There are two additional concerns raised by the *Buckman* Court that further undercut petitioners' claims. First, the *Buckman* Court worried that expanding liability by permitting novel claims like the fraud-on-the-FDA claim asserted by the *Buckman* plaintiffs might discourage the development of beneficial, but potentially risky, new products. *Buckman*, 531 U.S. at 350-51. This concern has no force here. The Michigan statute *limits* traditional common law liability; it does not create a new cause of action or expand liability under an existing cause of action. *See Taylor*, 658 N.W.2d at 131; *see also Desiano*, 467 F.3d at 94-95.

Second, the *Buckman* Court was concerned that expanding potential tort liability might create an "incentive for drug companies to submit a deluge of information that the [FDA] neither wants nor needs." *Id.* at 351. At least with the FDA's regulation of drugs, in contrast to the regulation of medical devices involved in *Buckman*, this concern is misplaced. It is hard to imagine what information a drug company might have that even tangentially relates to the safety of the drug that the company is not already required to submit to the FDA. *See* 21 C.F.R. § 314.50.[11]

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[11] FDA regulations are comprehensive, leaving no room for an applicant to omit information that might be relevant to the drug's approval. Among other things, the FDA requires a

(continued...)

Finally, petitioners' reading of subsection (a) of the Michigan statute as requiring a formal FDA finding of fraud or decision to withdraw approval for a drug on the basis of safety concerns would render the provision a dead letter. Neither petitioners nor their *amici* (including the United States) can cite a single instance in which the FDA took either measure. Nor can they point to an example where the FDA, once it took enforcement action, went on to declare what impact, if any, the misconduct had on its approval determination.

Petitioners' silence is unsurprising. The GAO reports that, "[s]ince 2000 there have been 10 drug withdrawals for safety reasons, and in all of these cases the drug's sponsor voluntarily removed the drug from the market." GAO Safety Report, *supra* note 2, at 10. The GAO goes on to note that the "FDA does not have explicit authority to require that drug sponsors take other safety actions," but when the FDA identifies a problem, "sponsors generally negotiate with the FDA to avoid other regulatory action." *Id.* And the FDA's own Science Advisory Board reports that the FDA has all but stopped bringing enforcement cases against manufacturers of approved drugs.[12] Thus, to find that

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[11](...continued)
company to submit, as a precondition to approval, an "integrated summary of *all* available information about the safety of a drug product . . .." 21 C.F.R. § 314.50(d)(5)(vi)(a) (emphasis added); *see also* § 314.80 (spelling out comprehensive reporting requirements for drugs post-approval).

[12] FDA Science Board, *Report of the Subcommittee on Science and Technology, FDA Science and Mission at Risk* (Nov. 2007), *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html. The decline in enforce-
(continued...)

the Michigan legislature intended subsection (a) to require formal FDA action would be to ascribe a singularly irrational intent on its part: namely, that it made a statutory trigger contingent on FDA action the agency rarely, if ever, takes.

III. The Court Should Remand The Severability Question.

The ruling below is correct and should be affirmed. If this Court disagrees, the case must be remanded for consideration of the severability question—that is, whether subsection (a) of Mich. Comp. Laws § 600.2946(5) is severable from the remainder of the statute, or whether the statute is invalid in its entirety. In AARP's view, there is a serious federalism problem that runs through this case. The statute at issue is a Michigan statute, yet because of the routine removal of cases to federal court, it has not yet been authoritatively construed by a Michigan court, apart from the Michigan Supreme Court's ruling in *Taylor* upholding the statute in the face of a challenge to its constitutionality under the Michigan Constitution.

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[12](...continued)
ment activities by the FDA is nothing short of stunning. In 1991, 1992, and 1993, the agency brought 468 civil seizure actions, 75 criminal injunction cases, and 121 criminal prosecutions; in 2004, 2005, 2006, and 2007, the agency bought just 53 civil seizure actions, 57 criminal injunction cases, and *zero* criminal prosecutions. *FDA Science and Mission at Risk*, at Appendix B-22 - B-23. Tellingly, the *only* FDA enforcement case petitioners or the United States cites, *United States v. Lane Labs*, 427 F.3d 219 (3d Cir. 2005), was *not* an action to withdraw approval of an approved drug. It was instead an action for injunctive and equitable relief against the sellers of *unapproved* drugs, namely shark cartilage and other products as cures for cancer and HIV infection.

We urge this Court to reject Warner-Lambert's argument that this Court should make the severability determination on its own and sever just subsection (a) from the remainder of Mich. Comp. Laws § 600.2946(5). For one thing, the severability issue is not subsumed within the question presented in this case and therefore is not before the Court. For another, such a Procrustean approach to severability would do violence to the Michigan statute's goal, which is to provide drug companies that play by the FDA's rules a complete regulatory defense, but to withdraw that defense when companies engage in conduct that taints the approval process. Severing just the portion of the statute Warner-Lambert urges would turn a strong-but-conditional defense into a blanket immunity and would give protection to drug companies far beyond that intended by the Michigan legislature. For this reason, in the event that the Court disagrees with the Second Circuit, we urge the Court to remand this case for reconsideration of the severability question.

CONCLUSION

For the reasons set forth above and in respondents' brief, the judgment below should be affirmed.

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No. 06-1498

IN THE

Supreme Court of the United States

WARNER-LAMBERT CO., LLC, ET AL.,

Petitioners,

v.

KIMBERLY KENT, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF FOR THE AMERICAN ASSOCIATION FOR JUSTICE AS AMICUS CURIAE SUPPORTING RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The American Association for Justice ("AAJ"), formerly the Association of Trial Lawyers of America, respectfully submits this brief as *amicus curiae* in support of Respondents. This brief is filed with consent of all parties.[1]

AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in personal injury cases and other civil actions, including product liability cases. Throughout its 60-year history, the association has advocated both in courts and in Congress and state legislatures to preserve the protections for ordinary citizens afforded by the common law and to ensure that state tort claims, such as product liability claims, provide injured persons with effective legal recourse and remedies for wrongful injuries. By bringing such claims on behalf of people injured by pharmaceutical products, among others, and also by testifying before Congress about drug safety and the FDCA, AAJ's members have helped to ensure that the nation's consumers have access to safe and effective pharmaceuticals.

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[1] Letters of consent from both parties have been filed with the Clerk of Court. Pursuant to Rule 37.6, *amicus* states that no counsel for a party authored any part of this brief, nor did any person or entity other than *amicus*, its members, or its counsel make a monetary contribution to its preparation or submission.

SUMMARY OF THE ARGUMENT

1. The Court of Appeals for the Second Circuit correctly held that this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), does not preempt the exemption to Michigan's statute shielding pharmaceutical manufacturers from products liability claims, Mich. Comp. Laws Ann. § 600.2946(5). Congress did not intend the FDCA to preempt state common law tort claims, such as those alleged by Respondents, none of which has as an element fraud or misrepresentation to the FDA. The application of Michigan's exemption in this case does not "inevitably conflict with the FDA's responsibility to police fraud," *Buckman*, 531 U.S. at 350, nor is there a "direct and positive conflict" between the exemption and the FDCA.

Michigan's statutory scheme is consistent with the FDCA. The State's conclusive statutory presumption that drug manufacturers are not liable for state products liability claims applies only to drug manufacturers who comply with FDA protocols; the exemption challenged here applies only in cases in which a drug manufacturer withheld information from or misrepresented information to the FDA during the drug approval process.

When a plaintiff does not proffer evidence of misconduct, a court will dismiss a plaintiff's products liability action. In a case such as Respondents', however, in which evidence of such wrongdoing exists, such evidence merely permits Respondents' state law tort claims to proceed. Unlike *Buckman*, evidence of wrongdoing in the FDA drug-approval process does not compose any part of any tort claim

alleged by Respondents, and will not factor in the subsequent litigation, nor will it impact, impel, or result in any further action by the FDA.

2. State tort claims, such as those brought by Respondents, work in concert with FDA regulation to ensure that the public has access to safe and effective drugs. As an FDA-commissioned Institute of Medicine Report noted, drugs approved by the FDA enter the market with incomplete safety profiles. The FDA, however, lacks adequate tools to address the postmarketing safety issues that inevitably result. The FDA lacks the authority to require postmarketing safety studies and does not systematically document reports of adverse reactions, which generally are submitted at the discretion of the drug manufacturer. Furthermore, the FDA is underfunded and overburdened, as a result of which the FDA's rate of prosecuting enforcement actions declined by sixty-six percent between 2000 and 2005.

Congress understood that litigation plays an essential role in identifying key information concerning drug safety and efficacy, as well as in providing remedies to consumers who suffer drug-related injuries. The Michigan exemption, which would permit tort claims to proceed against a drug manufacturer *only* in cases in which the manufacturer withheld or misrepresented information during the drug approval process, does not conflict with the FDCA and thus should not be held preempted under *Buckman*.

ARGUMENT

I. The Exemption to Michigan's Statute Shielding Drug Manufacturers From Liability Is Not Impliedly Preempted by the FDCA

All states provide legal remedies to consumers who are injured by unreasonably dangerous products, including pharmaceuticals. State legislatures have modified common law products liability to varying extents to serve a range of state interests.

Michigan law provides that a drug manufacturer whose product has received FDA approval cannot be liable in a products liability action, unless the manufacturer obtained that approval by withholding or misrepresenting information to the FDA. Mich. Comp. Laws Ann. § 600.2946(5); *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 130 (Mich. 2003). The statute's conclusive presumption of non-liability – and the exemption thereto at issue here – are valid exercises of state legislative authority. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (explaining that because health and safety are "primarily, and historically, . . . matter[s] of local concern," the "States traditionally have had great latitude under their police powers to legislate" on such matters) (quotations omitted). That Michigan chooses to presume that pharmaceutical manufacturers are not liable for product liability claims when the manufacturer has complied with FDA protocols – and to deny that presumption to those manufacturers who violate those procedures by willfully withholding information from, or

misrepresenting information to, the FDA – is entirely a matter of state rather than federal law. *See id.* It also is a function of the historic distribution of power between the States and federal government as separate sovereigns under our Constitution.

The Court of Appeals for the Second Circuit correctly held that the exemption to Michigan's statute shielding pharmaceutical manufacturers from products liability, Mich. Comp. Laws Ann. § 600.2946(5), is not impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). As the lower court noted, the claims at issue in *Buckman* were novel state-law claims alleging that a consulting company that helped a medical device manufacturer gain FDA approval for its device committed fraud on the FDA. By contrast, Respondents assert common law claims, including breach of implied and express warranties, negligence, and defective design and manufacturing claims. Pet. App. at 7a. Respondents' claims neither are "premised on fraud against the FDA," nor seek to hold a drug manufacturer liable under state law for alleged misrepresentations to the FDA. *Compare Buckman*, 531 U.S. at 345-47. Respondents' common law claims also are not themselves "preempted" by the FDCA, as were those alleged in *Buckman*. *See* Pet. App. at 19a.

The exemption to Michigan's presumption of non-liability that Respondents' seek to apply here is not akin to those claims held preempted in *Buckman*. *Buckman*, 531 U.S. at 353. "In [*Buckman*], the fraud claims exist solely by virtue of the FDCA disclosure requirements." *Id.* Respondents' claims, by comparison, are not premised on "[p]olicing fraud

against" the FDA, nor do they exist "solely by virtue of the FDCA." *Compare id.*

The Michigan exemption reflects the legislature's decision to allow only a limited class of product liability claims to proceed against drug manufacturers. Those cases, in which evidence demonstrates that the drug manufacturer withheld information from, or misrepresented information to, the FDA, neither implicate this Court's ruling in *Buckman*, nor interfere with the FDA's policing of fraud. In fact, they are consistent with the FDA's anti-fraud provisions and reinforce the FDA's purposes by providing a further disincentive to drug manufacturers to breach FDA protocols, by withholding or misrepresenting information during the drug approval process. Compliance with FDA protocols confers nonliability in Michigan.

The Michigan exemption is a *precondition* to holding a drug manufacturer liable under Michigan's product liability laws, just as service of process is a precondition to suit. A judge's decision whether to apply the exemption and permit a plaintiff's state tort claims to proceed to trial neither implicates action by the FDA, nor interferes with FDA functions. The determination is based largely on the court's review of documents submitted to the FDA by the drug manufacturer or that have come to light post-marketing, and the ultimate FDA actions concerning the drug. *See, e.g.*, Liza Gibson, *GlaxoSmithKline to Publish Clinical Trials After US Lawsuit*, 328 Brit. Med. J. 7455 (Jun. 26, 2004) (discussing lawsuit brought by New York Attorney General alleging that drug manufacturer "engaged in 'repeated and persistent fraud' for concealing" results of clinical studies and citing company memo that it

would be "commercially unacceptable" to admit results). Such an inquiry would not burden the FDA.

A court's finding a drug manufacturer committed wrongdoing during the drug approval process sufficient to allow the lawsuit to proceed would have no legal consequences for the FDA. It does not override or replace a judgment by the FDA. It does not obligate the FDA to take action related to the finding. Most importantly, it does not itself result in liability for the drug-manufacturer defendant. It merely opens the door to the courtroom.

Applying Michigan's exemption in this way does not "inevitably conflict with the FDA's responsibility to police fraud," *Buckman*, 531 U.S. at 350, nor does it infringe or "direct[ly] and positive[ly] conflict" with the FDCA, as this Court held the claims did in *Buckman*. Application of the exemption neither renders compliance with the FDCA "a physical impossibility" nor "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of the FDCA. Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 228 (2000) (citations omitted). Instead, the Michigan exemption and the showing required by the statute are completely consonant with federal law.

By comparison, a finding by this Court that the Michigan exemption *is* preempted would interfere with Congress's purposes in enacting the FDCA. Allowing drug manufacturers, who have misrepresented or withheld information during the drug approval process, to avail themselves of a conclusive presumption of non-liability and thus be immune from suit would destroy a powerful,

complementary incentive to comply with FDA procedures and would limit FDA's access to crucial information. Such interference would impede the FDA's ability to fulfill its regulatory mission, as the agency itself recognizes.[2] *See* 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006) (stating that state tort claims should not be preempted if "the [drug's] sponsor withheld material information" from the FDA).

II. Congress Did Not Intend the FDCA to Preempt State Tort Liability for Harm Caused by Unreasonably Dangerous Drugs

This Court should affirm the Second Circuit's decision that the application of Michigan's exemption to Respondents' claims does not conflict with and is not preempted by the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, *et seq.* First, Congress did not intend the FDCA to preempt state tort claims. Congress intended to preserve traditional state tort claims to provide remedies for persons who wrongly suffered drug-related injuries and to supplement the FDA's regulatory authority. Second, Congress intended the FDCA to preempt state law only where state law poses a "direct and positive conflict" with the FDCA. The exemption to the Michigan statute does not pose a direct and positive conflict with the FDCA or undermine FDA's ability to police fraud.

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[2] This assumes for argument that the exemption is severable. Whether the exemption provision is severable is an open question, discussion of which is beyond the scope of this brief.

A. Congress Did Not Intend the FDCA to Preempt State Tort Claims

Congress's intent provides the "touchstone" in matters of federal preemption. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Courts ascertain that intent from the plain wording of a preemption provision, *Medtronic*, 518 U.S. at 484; *Cipollone*, 505 U.S. at 523-24, as well as from "both textual and legislative context" of the statute, *Medtronic*, 518 U.S. at 489-90; *Cipollone*, 505 U.S. at 519 n.16.

Petitioners urge the Court to hold that the application of the Michigan exemption is impliedly preempted under *Buckman*, thus barring Respondents' state law claims seeking remedies for drug-related injuries. The Michigan exemption, however, is an exemption to a statute enacted within Michigan's legislative prerogative in a "field which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485; *compare Buckman*, 531 U.S. at 347. Because both the exemption to the Michigan statute and Respondents' underlying claims, unlike those at issue in *Buckman*, involve a "'field which the States have traditionally occupied,'" the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *Jones v. Rath Packing Co.*, 430 U.S. 519, 544-45 (1977) (Rehnquist, J., concurring).

The Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 301, *et seq.*,[3] does not contain a general express preemption provision for pharmaceutical products as codified. *Jones*, 430 U.S. at 537; *see also* 71 Fed. Reg. 3935 n.8. The legislative history of the FDCA, its amendments, and its predecessor the Pure Food and Drug Act of 1906, however, reflect Congress's intent that the FDCA not infringe on state common law causes of action.

In 1938, after the deaths of more than 100 people from elixir of sulfanilamide, Congress passed the FDCA, Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 22, 152 (Alina Baciu, et al. eds. 2007) ("IOM Report"), to regulate producers of dangerous products and to protect consumers. *See United States v. Dotterweich*, 320 U.S. 277, 280, 282 (1943) (stating that House and Senate committee reports indicate that "[t]he purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection"); *see also 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951) (stating that Congress intended the FDCA to protect consumers); *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

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[3] When the FDCA was enacted, Congress repealed the Pure Food and Drug Act of 1906, Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906), codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 329(a)). *See* Marden G. Dixon & Frank C. Woodside III, Drug Product Liability § 5.01 [1] (1982). Prior to the enactment of the Pure Food and Drug Act of 1906, "the States provided the primary and possibly the exclusive source of regulatory control over the labeling of foods and drugs." *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 782 (E.D. La. 2007).

"The act prohibited false therapeutic claims for drugs and for the first time required premarket notification of FDA by the sponsor for all new drugs. . . . [I]t did not require proof of efficacy." IOM Report, *supra*, at 22.

Congress considered including in the Act a private federal cause of action for damages caused by faulty or unsafe products regulated by the Act. *See* H.R. Rep. No. 73-6110, pt. 1, § 25 (1933) ("Liability for Personal Injuries – a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act."). Notably, the Senate deleted this proposed private cause of action from the bill on the ground that it is unnecessary because "[a] common-law of right of action exists" in state law. Hearing on S. 1944 Before a Subcomm. of the Comm. on Commerce, 73d Cong. 2d Sess. 400, 403 (1933). *See also Consumer Fed'n of Am. v. Upjohn*, 346 A.2d 725, 731 (D.C. 1975) (explaining that private right of action was omitted from bill because "it would create an *unnecessary* federal action *duplicative of state remedies*" and concluding that Congress "*rejected* [] setting up a nationally uniform law for such" actions) (emphasis added); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n.130 (1994).

A common law cause of action for negligence with respect to the manufacture and sale of medicines and related products was long-standing and widely recognized. *See, e.g., Boyd v. Coca Cola Bottling Works*, 177 S.W. 80, 81 (Tenn. 1915) (holding that drug, food, and beverage manufacturers owe a duty to those who consume their products and that "[a] tort is committed, a legal

right invaded, by practices which prejudice another's health"); *Thomas v. Winchester*, 2 Seld. 397, 1852 WL 4748 (N.Y. 1852) (holding a drug manufacturer liable for a patient's injury); *see also* Restatement (Third) of Torts Prod. Liab. § 2 (1998) (providing standards of liability when a product is defective).

That Congress passed the FDCA without a private right of action indicates that Congress intended state tort actions to be maintained both to provide "judicial recourse for those injured" by pharmaceutical products and to accomplish the purposes of the FDCA. *Compare Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("This silence [of Congress in enacting and amending the Atomic Energy Act] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."). *See also Medtronic*, 518 U.S. at 487 (citing same in construing 21 U.S.C. § 360k(a) of the Medical Device Amendments).

In Europe, in the late 1950s and early 1960s, thousands of children were born with birth defects to mothers who had ingested thalidomide. IOM Report, *supra*, at 22, 152; *see also* Richard S. Jacobson & Jeffrey R. White, *David v. Goliath: ATLA and the Fight for Everyday Justice* 153-55 (2004). Thalidomide's approval by the FDA was pending when the adverse effects of the drug in Europe came to light. Because of this "near miss" – but for a delay in the approval process many thousands of children in the U.S. likely would have been born with disfiguring birth defects – Congress initiated

amendments to strengthen the FDCA in 1962.[4] *See* S. Rep. No. 1744, 87th Cong., 2d Sess., at 1 (1962) ("The purpose of the proposed legislation . . . is to strengthen and broaden existing laws in the drug field so as to bring about better, safer, medicine and to establish a more effective system of enforcement of the drug laws."); *see also* Jacobson & White, *supra*, at 153-55 (discussing ATLA members' representation of thalidomide victims and their role in Congressional hearings on strengthening the FDCA).

The 1962 Drug Amendments "shifted the burden of proof from FDA (which previously had to prove harm to keep a drug from being marketed) to manufacturers, who now were required to demonstrate both safety and efficacy prior to receipt of marketing approval." IOM Report, *supra*, at 152 (citation omitted). Nevertheless, the "FDA's ability to form judgments about the safety and efficacy of drugs depends upon the submission of data, usually from drug company sponsors, rather than on the use

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[4] In recent years, the FDA has not been so lucky in avoiding adverse events. Pharmaceutical companies are not required to report "adverse events identified in non-US marketing experience unless the events are 'serious and unexpected.'" Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 310 (Jan. 17, 2007). In 1995, Belgian authorities informed FDA that women who used diet drugs such as dexfenfluramine (Fen-Phen) had heart valve abnormalities. Because the FDA did not monitor reports of adverse effects made to its international counterparts, and the drug manufacturer did not provide case reports to the FDA, the FDA did not consider the earliest adverse events related to the drug. *Id.* Ultimately, the drug was withdrawn from the U.S. market after many consumers suffered injuries when Fen-Phen's "risk of causing cardiac valvulopathy and pulmonary hypertension was determined to outweigh its very modest capacity to promote weight loss." *Id.*

of data developed independently or on its own initiative." *Id.*

The 1962 amendments also clarified the FDCA's intended effect on state laws. Congress included language explicitly *restricting* the potential preemptive effect of federal law to cases of "direct and positive conflict": "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating *any* provision of State law which would be valid in the absence of such amendments unless there is a *direct and positive conflict* between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (emphasis added).

This Court found in *Buckman* such a direct and positive conflict in a fraud-based cause of action. However, extending *Buckman* to preempt the Michigan exemption would undermine the FDCA. As another federal district court has written, in rejecting a similar preemption argument:

> FDA's and [defendant]'s position [in favor of preemption] vitiates, rather than advances, the FDCA's purpose of protecting the public. That is, FDA and [defendant] invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action but also eliminated the availability of common law state claims. This position contravenes common sense . . . .

In re Paxil Litig., No. 01-07937, 2002 WL 31375497 at *1 (C.D. Cal. Oct. 18, 2002).

The Court's inquiry here into whether application of the Michigan exemption to Respondents' claims is preempted under *Buckman* should not be "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in part and dissenting in part) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment)). Instead, the Court should reaffirm that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) (internal quotation omitted).

Congress was fully aware of the existence – and usefulness – of state laws addressing drug safety and tort law remedies when it enacted and amended the FDCA. Congress, however, has *never* sought to preempt such actions.[5] As the former Commissioner of the Food and Drug Administration has written,

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[5] Congress recently amended the FDCA by enacting the Food & Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823 (2007). The sole preemption language included in the FDAAA precludes States or political subdivisions from "establish[ing] or continu[ing] in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database." 42 USCA § 282(d)

"Nothing in the statutes the FDA administers suggests that they eliminate state damages actions for pharmaceutical products. . . . And Congress *has not acted* to preempt or limit state damage actions, even though it has long been aware of tort litigation over drug products." David A. Kessler, M.D. & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. __ (forthcoming Jan. 2008) (emphasis added), *available at* http://lsr.nellco.org/georgetown/ois/papers/2/. Courts have noted that "[i]f Congress wants to take the extraordinary step of giving drug manufacturers immunity from personal tort actions, it would expressly state such intentions whether by statute or legislative history." *Merrell Dow Pharms., Inc. v. Oxendine*, 649 A.2d 825, 829 (D.C. 1994) (quoting *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1299-1300 (D. Minn.1988)) (ruling that FDCA did not preempt state tort law actions against manufacturers of prescription drugs).

This Court should decline to shield Petitioner from liability under Michigan law by preempting application of the Michigan exemption. Such a result would contradict Congress's intent in enacting the FDCA. Michigan's enactment of a conclusive presumption of non-liability for drug manufacturers, which bars all claims for drug-related injuries except those relating to drugs whose manufacturers misrepresented information to, or withheld information from, the FDA, is a legislative choice in a traditional state field of interest. Such legislation is Michigan's prerogative and should be respected by this Court.

B. No "Direct and Positive Conflict" Exists Between the Michigan Exemption and the FDCA

When Congress's express words provide "a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to preempt state laws." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). As discussed above, the FDCA "does not contain an express statement that Congress intended to displace state-law claims in the prescription drug context." *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d at 784. To the contrary, the 1962 Drug Amendments expressed Congress's intent that the FDCA *not* preempt state law "unless there is a *direct and positive conflict* between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (emphasis added).

Congress inserted the "direct and positive conflict" language in the 1962 Drug Amendments to avoid claims of preemption and to leave state law in place except in cases in which it was impossible to comply with both state and federal laws. *Levine v. Wyeth*, --- A.2d ----, 2006 WL 3041078 at ¶27 (Vt. 2006), *petition for cert. filed* (U.S. Mar. 12, 2007) (No. 06-1249). *See also Southern Blasting Servs., Inc. v. Wilkes County, N.C.*, 288 F.3d 584, 590 (4th Cir. 2002) (interpreting statute disclaiming preemption except in cases of "direct and positive conflict" and explaining that state law is preempted *only* when it is in "*actual* conflict with federal law such that 'compliance with both federal and state regulations is a physical impossibility") (citing *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S.

707, 713 (1985) (internal quotation omitted)) (emphasis added).

Congress understood the "direct and positive conflict" language to ensure that federal law will not widely preempt state law in fields such as food and drug law where states have stronger laws and tort causes of action to remedy injuries. *Merrell Dow Pharms., Inc. v. Oxendine*, 649 A.2d 825, 828 n.3 (D.C. 1994) (citing 108 Cong. Rec. 21,083 (1962)). *See also Thrall v. Wolfe*, 503 F.2d 313, 317 (7th Cir. 1974) (interpreting statute with *identical* "direct and positive conflict" language and concluding, "The section was doubtless inserted for the purpose of avoiding a claim of preemption"); *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d at 784, 788-89 (discussing 1962 amendments; holding plaintiffs' claims not to be preempted by FDCA). Courts have held accordingly that this language in the 1962 Amendments "essentially removes from our consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress." *Levine*, 2006 WL 3041078 at ¶ 27.

"For a direct and positive conflict to exist, the state and federal laws must be such that they 'cannot be reconciled or consistently stand together.'" *Southern Blasting Servs., Inc.*, 288 F.3d at 590; *see also Sinnot v. Davenport*, 63 U.S. 227, 243 (1859).

> [A] state[]'s imposition of additional requirements *above* a federal minimum is *unlikely* to create a direct and positive conflict with federal law. Rather, a conflict is more likely to occur when a state [] provides that compliance

> with a federal standard is not mandated, or when compliance with federal law actually results in a violation of local law.

Southern Blasting Servs., Inc., 288 F.3d at 591-92 (emphasis added). *Compare Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 141 (1963) (holding that a California statute did not "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' . . . [because] there is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of a congressional design to preempt the field") (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

This Court should not hold that there is "a *direct and positive* conflict between [the 1962] amendments" to the FDCA and state law – the Michigan exemption for two reasons. First, the limited showing of misconduct necessary to satisfy the exemption does not amount to an "additional requirement[] above a federal minimum." *Southern Blasting Servs.*, 288 F.3d at 591. A plaintiff seeking to persuade a court that a defendant drug manufacturer's misconduct during the drug approval process falls within the exemption need only show that the defendant engaged in conduct already proscribed by federal law. The exemption does not amount to an "additional" or even a different requirement than the FDCA's. *See Medtronic*, 518 U.S. at 495 (holding that state law remedy does not impose an additional requirement but "merely provides another reason for manufacturers to comply with . . . federal law"). Second, the exemption

demonstrates that Michigan favors and indeed creates incentives for "compliance with federal law" rather than penalizes or discourages compliance with federal law because Michigan allows liability *only* in those cases in which drug manufacturers have not complied with federal law.

The Michigan exemption does not interfere with the federal regulatory scheme for prescription drugs, as did the claims at issue in *Buckman*. Rather, the exemption and federal regulations "consistently stand together." Moreover, the FDA has recognized that such an exemption is appropriate and consonant with its mandate. *See* Preamble to Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006) (stating that state tort claims should not be preempted if "the [drug's] sponsor withheld material information" from the FDA).

III. Congress Intended State Tort Claims to Complement the FDA's Regulatory Authority

A. The FDA's Regulatory Structure and Its Limited Resources Create Safety and Information Gaps That Harm Consumers

The FDA's regulatory emphasis on new drug development and getting drugs to market, and its lack of authority over drugs and drug manufacturers postmarketing, creates safety and information gaps that Congress understood and anticipated would be filled by state tort claims, to some important extent. The FDA's regulatory scheme is consistent with

others created by Congress that rely on postmarketing liability not only to provide compensation for wrongful injuries but to inform and complement federal regulation. *See CSX Transp., Inc. v. Easterwood,* 507 U.S. 658, 668 (1993) (explaining state "negligence liability could just as easily complement" regulations under statute); *Silkwood,* 464 U.S. at 264 (Blackmun, J., dissenting) (stating that tort damages "complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme"); *Larsen v. General Motors Corp.*, 391 F.2d 495, 506 (8th Cir. 1968) ("It is apparent that the National Traffic Safety Act is intended to be supplementary of and in addition to the common law of negligence and product liability."); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1493 (D. Kan. 1987) (state tort actions actually enhance the statutory goal of optimum vaccine safety).

The FDA's regulatory authority is "structured around the *premarketing* testing process; few tools are available for addressing *postmarketing* safety issues, short of the blunt instruments to respond to clear-cut adulteration and misbranding." IOM Report at 153 (emphasis added).[6] Postmarketing

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[6] Relying on many of the Institute of Medicine's recommendations, Congress recently amended the FDCA to increase FDA's resources to ensure drug safety and its postmarketing power and authority. *See* Food & Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823 (2007); *see also* Bruce M. Psaty & David Korn, *Congress Responds to the IOM Drug Safety Report – In Full*, 298 JAMA 2185 (Nov. 14, 2007). Experts caution that even with the enactment of FDAAA, "drugs with unrecognized toxicity will reach the market." Psaty & Korn, *supra*, at 2187. FDAAA's ultimate success depends both on cooperation

safety issues, such as those for which Respondents seek remedies, however, are quite common: "Fifty-one percent of all [FDA] approved drugs elicit at least one serious type of adverse reaction that was not observed during premarketing clinical trials . . . 20 percent of new drug labels are modified with a black box warning; 3 to 4 percent of new drugs are withdrawn for safety reasons." Thomas N. Tiedt, *The Drug Safety System Conundrum*, 62 Food & Drug L.J. 547, 553 (2007).

Postmarketing safety issues arise because drugs enter the U.S. market with "incomplete safety profiles," IOM Report at 37. "Pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately representing in the studies (*e.g.*, the elderly, ethnic minorities and pregnant women)." Kessler & Vladeck, *supra*, at 12 (citing IOM Report at 38). Premarketing clinical trials are highly managed and enroll patients who "generally have more homogenous medical histories" and represent a more limited demographic. Tiedt, *supra*, at 553. As a result, adverse drug reactions are constrained and more infrequent than they would be in a general population. *Id.* As an FDA-commissioned report by the Institute of Medicine explains:

> Preapproval trials typically are too small to detect even significant safety problems if they are rare. An adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot

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between industry, academia and the FDA, and the FDA increasing its leadership and oversight. *See id.*

> be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug.

IOM Report at 37-38 (citations omitted). Unfortunately, changes to clinical trial protocols and their sizes likely will not prevent drugs from entering the market with incomplete safety profiles. As experts have explained, "[t]rials designed to test hypotheses about serious safety outcomes would in most cases require many more subjects than are needed for an efficacy endpoint." IOM Report at 106.

The case of Rezulin (troglitazone), the drug at issue here, is not an isolated example of these systemic failures. *See, e.g.*, IOM Report at 17 ("Alosetron was withdrawn . . . Troglitazone, propulsid, cerivastatin, rofecoxib, and valdecoxib have been withdrawn."); *see also* Amalia M. Issa, *et al.*, *Drug Withdrawals in the United States: A Systematic Review of the Evidence and Analysis of Trends*, 2 Current Drug Safety 177 (Sept. 2007) (finding that a mean of 1.5 drugs per year (or twenty drugs) were withdrawn since 1993). The clinical trial of Rezulin involved 2510 patients who received Rezulin; an additional 475 patients received placebo. Paul B. Watkins, M.D., *Hepatic Dysfunction Associated with Troglitazone*, 338 New Eng. J. Med. 916-17 (Mar. 26, 1998). Of the patients taking rezulin, 48 (1.9%) had abnormal liver tests, meaning that they had enzyme elevations of more than three times the upper limit of normal. *Id.* Some patients' "enzyme elevations were more than 20-fold greater than normal and [] several patients developed severe liver failure." Aaron S. Kesselheim & Jerry Avorn,

The Role of Litigation in Defining Drug Risks, 297 JAMA 308, 310 (Jan. 17, 2007). During the clinical trial, twenty patients withdrew from the trial and stopped receiving Rezulin because of their abnormal "liver-chemistry values." *Id.*

The "FDA's ability to form judgments about the safety and efficacy of drugs *depends* upon the submission of data, usually from drug company sponsors, rather than on the use of data developed independently or on its own initiative." IOM Report at 152. Thus, although the adverse effects occurred during the Rezulin trial, because Petitioner "did not acknowledge this clinically important difference until more than a year after the drug was marketed," the FDA could not evaluate the adverse reactions and the drug's risks. Kesselheim & Avorn, *supra*, at 309-10. Moreover, when Petitioner presented the data to the FDA, Petitioner "minimized its presentation of [these] adverse effects by not considering the reason patients dropped out of placebo-controlled clinical trials." *Id.* (citation omitted).

The adverse effects, which occurred in only a limited number of patients at the clinical trial stage, were amplified – and thus more prevalent – once Rezulin went on the market, where it was used reportedly by more than one million patients. David Willman, *'Fast-Track' Drug to Treat Diabetes Tied to 33 Deaths*, L.A. Times, Dec. 6, 1998 at A1; *see also* Kessler & Vladeck, *supra*, at 12-13 (citing William B. Schultz, *How to Improve Drug Safety*, Washington Post, Dec. 2, 2004; *In re Vioxx Prods. Liab. Litig.*, 2007 U.S. Dist. LEXIS 43867 (E.D. La. July 3, 2007)). After the first Rezulin-related deaths were reported in 1997, an "FDA medical officer, Dr. Robert I. Misbin, estimated that more than 12,000 Rezulin

users would experience some liver injury. Misbin also advised his superiors that 2,000 of those patients might die . . . ." *Id.* At the time of its withdrawal, the FDA had conclusively linked 91 liver failures to the pill and reports cited Rezulin as a suspect in 391 additional deaths. David Willman, *The New FDA How a New Policy Led to Seven Deadly Drugs*, L.A. Times, Dec. 20, 2000, at A1. The safety limitations of a drug are compounded when a drug manufacturer does not report or acknowledge adverse events during the clinical trial phase to the FDA, as occurred here, Kesselheim & Avorn, 297 JAMA at 310, and in the case of Paxil, among others, Gibson, *supra*, at 7455.

Congress anticipated and the FDA and other government agencies recognize that "FDA approval does not represent a lifetime guarantee of safety and efficacy." IOM Report at 2. Indeed, it cannot. "While only a few thousand patients are exposed to the new drug in aggregate before approval, millions of patients, many of whom have significantly more complex medical histories than those studied prior to approval, will ultimately use the drug in intended as well as untested circumstances" after the drug is on the market. Tiedt, *supra*, at 553. Thus, many more adverse events occur once a drug is on the market. *See, e.g.*, IOM Report at 17 (listing drugs), 109-10 (same and describing flaws in FDA's system for identifying and addressing such adverse events);

The FDA lacks a systematic means of collecting reports of adverse reactions, *id.* at 109, and what procedures exist are plagued by conflicts of interest, Tiedt, *supra*, at 553. Under the FDCA, at the time of Respondents' suit, "the detection, evaluation, and timely reporting of postmarketing

safety issues [were entrusted] to the pharmaceutical industry." Bruce M. Psaty & David Korn, *Congress Responds to the IOM Drug Safety Report – In Full*, 298 JAMA at 2185.[7] More than "90 percent of the adverse reaction reports submitted to FDA come from the new drug's marketer, who may have an inherent economic conflict of interest in drug safety decisions." Tiedt, *supra*, at 554 (citation omitted). The drug manufacturer has a disincentive to "acknowledge a risk or [] to implement studies to quantify the risk." *Id.* In fact, investigators from the FDA's Center for Drug Evaluation and Research stated that "there are strong disincentives for companies . . . to identify safety problems with licensed drugs quickly and efficiently. . . . Seeking out and sharing bad news about a product are unlikely to increase business." *Id.* (citations omitted).

That FDA approval does not indicate that the drug is necessarily safe and effective has become even more true since Congress enacted the Prescription Drug User Fee Act of 1992 ("PDUFA"), which sought to expedite agency decision-making by requiring that drug review be completed in 180 days. IOM Report at 154-55. As the FDA has struggled to meet PDUFA's goals, it has become "hard or close to impossible for [] reviewers to pursue safety concerns as carefully as they would in a less frenetic setting." *Id.* at 155 (citations omitted). Moreover, PDUFA's fee structure has contributed to commentators' and regulators' concerns that the FDA "has been 'captured' by industry it regulates [and] that the

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[7] The FDAAA of 2007 has sought to change this by giving the "FDA the authority to require postmarketing studies to identify or assess potential serious risks." Psaty & Korn, *supra* at 2185.

agency is less willing to use the regulatory authority at its disposal." *Id.*

Of most profound concern for safety and efficacy is that once the FDA has approved a drug, it has "few tools" to regulate drugs after they are released on the market. FDA has "limited authority after marketing" and is unable "to enforce implementation and fulfillment of important and necessary postmarketing commitments . . . ." *Id.* at 156 (citation omitted). As discussed above, FDA lacks "the authority to mandate further collection of data to better define adverse effects or to ensure compliance with suggested alterations in marketing practices." Kesselheim & Avorn, *supra*, 308. It also lacks authority to require postmarketing studies except in very limited cases (accelerated approval); of those requested, "47% of annual reports on studies that were due were not submitted to FDA." IOM Report at 156. According to the Office of the Inspector General, "FDA has no recourse when sponsors do not make progress or do not report on their commitments." *Id.* (citations omitted).

FDA's "resources for postmarketing drug safety work are especially inadequate and [] resource limitations have hobbled the agency's ability to improve" and perform such work. IOM Report at 193. The FDA's lack of resources and authority to induce marketers to perform postmarketing safety studies, and its incomplete system for collecting reports on adverse events, necessitates that an additional mechanism exist to ensure that the drugs on the market are safe and effective. This role is filled primarily by litigation and the civil justice system. *See generally* Kesselheim & Avorn, *supra*, at 308-311. Because of litigation's crucial role in

"uncover[ing] important and previously unavailable data about major adverse events," *id.* at 308, and providing a remedy to patients who suffer drug-related injuries, of which Congress was aware, *see supra* at 11-12, 16, the Court should not preempt application of the Michigan exemption to Respondents' claims under *Buckman*. Such an action not only would bar Respondents' state tort law claims but those of all Michigan residents who have suffered drug-related injuries from drugs produced by manufacturers who wrongly misrepresented or withheld information during the drug approval process.

B. State Tort Liability Provides a Necessary and Intended Complement to Regulation in Achieving Congress's Goal of Safe and Effective Pharmaceuticals

Litigation is crucial to ensure the safety and effectiveness of drugs because, as Congress recognized, FDA approval is not a guaranty of safety or efficacy and the FDA historically has lacked the tools to fully and adequately regulate drugs after they are on the market. The FDA's reach is enormous, regulating products that represent roughly 25 percent of all consumer spending in the United States. Institute of Medicine, Challenges for the FDA: The Future of Drug Safety, Workshop Summary (2007). In other words, FDA regulates "approximately $1 trillion in consumer products or 25 cents of every consumer dollar expended in this country annually." FDA Subcommittee on Science & Technology, *FDA Science & Mission at Risk* 1 (Nov. 2007). Yet, as the FDA itself has concluded, it has

"serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." *Id.* at 2-3. The FDA is underfunded and overburdened, Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. Mich. J.L. Reform 461, 496 (1997), as a result of which the FDA's rate of prosecuting "enforcement actions [] declined by sixty-six percent between 2000 and 2005," U.S. House of Rep., Comm. on Gov. Reform, *Prescription for Harm: The Decline in FDA Enforcement Activity* 8-9 (Jun. 2006) (Minority Report prepared for Rep. Henry Waxman).

Congress intended the civil justice system to supplement regulation, *see supra* at 11-12, 16. Litigation has fulfilled this purpose. *See In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571, 575 (E.D.N.Y. 2007) ("[L]awyers and their clients often find themselves serving as drug safety researchers of last resort.") (quotation omitted). Litigation has "helped the medical community reassess drugs by bringing to light new information about adverse effects" and "[i]n both the premarketing and postmarketing stages, lawsuits have helped uncover important and previously unavailable data about major adverse events." Kesselheim & Avorn, *supra*, at 308. Additionally, the "legal system [has] played an important role in spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators." *Id.* at 310.

Product liability claims, such as those alleged by Respondents, work in concert with federal regulation, allowing the marketplace to provide an

added financial incentive for manufacturers to make their products safe and effective as mandated by the FDA. See John W. Wade, *On the Nature of Strict Tort Liability for Products,* 44 Miss. L.J. 825, 826 (1973); (Pet'r App. at 25a-26a). Regulation and liability, in fact, are understood by this Court to be complementary. *See, e.g., CSX Transp., Inc.,* 507 U.S. at 668 (explaining state "negligence liability could just as easily complement" regulations under statute); *Silkwood,* 464 U.S. at 264 (Blackmun, J., dissenting) (stating that tort damages "complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme").

By assessing risk retrospectively, product liability helps to compensate consumers for imperfect information. Steven P. Croley & Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683, 707-08 (1993); *see also* W. Kip Viscusi, *Reforming Products Liability* 66 (1991) ("The purpose of products liability is to fill the gaps left by market imperfections and to replicate the incentives that would have been generated had markets been functioning perfectly.") State tort claims fulfill this role directly, by providing remedies to people who suffer adverse reactions to drugs, and also indirectly, by creating financial incentives for pharmaceutical companies to make their products safer and to provide more reasonable warnings to the FDA and to consumers about the dangers those products pose. As the former Chief Counsel of the FDA, Margaret Jane Porter, has written, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Margaret J. Porter, *The Lohr*

Decision: FDA Perspective and Position, 52 Food & Drug. L.J. 7, 11 (1997).

State tort claims, including Respondents' claims, further the purposes of the FDCA, as discussed above. As the Supreme Court said in *Bates* about a statutory scheme similar to the FDCA, "[p]rivate remedies . . . seem to aid, rather than hinder, the functioning of FIFRA . . . . [T]ort suits can serve as a catalyst in this process." 544 U.S. at 451.

Bates is consistent with numerous prior decisions holding that common law claims do not conflict with federal law because they merely exert incidental regulatory pressure on manufacturers. *See, e.g., English v. Gen. Elec. Co.*, 496 U.S. 72, 85-86 (1990) (upholding employee whistleblowers state law claim for intentional infliction of emotional distress against nuclear industry employer because effect of damage awards was not direct or substantial enough to warrant preemption); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 186 (1988) (upholding nuclear worker's state workers compensation claim based on violation of state safety regulation on the ground that compensation award imposes only acceptable incidental regulatory pressure, not unacceptable "direct regulatory authority"); *see also Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1542 (D.C. Cir. 1984) ("Compliance with both federal and state law cannot be said to be impossible. Chevron can continue to use the EPA-approved label and can at the same time pay damages to successful tort plaintiffs such as Mr. Ferebee").

As the Supreme Court has frequently observed, tort law often informs regulatory decisions,

and the FDA has often acted in response to information that has come to light in state damages action." Kessler & Vladeck, *supra*, at 21 (citing *Bates*, 544 U.S. at 451; Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings & Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002); Kesselheim & Avorn, *supra*, at 310.

The FDA recognized that its regulatory efforts benefited from and were supplemented by state product liability litigation. The FDA

> view[ed] that its regulatory efforts could coexist with state-law damages claims by consumers injured by drugs. As the agency saw it, state-law [] litigation *did not* interfere with the agency's regulatory efforts. . . . State damages litigation helps uncover and assess risks that are not apparent to the agency during a drug's approval process. Until recently, in the FDA's view, this "feedback loop" enabled the agency to better do its job. The agency also wanted to avoid the "harsh implications" of eliminating judicial recourse for consumers injured by dangerous drugs.

Kessler & Vladeck, *supra*, at 3 (emphasis added) (citing Porter, *supra*, at 9); FDA, *Prescription Drug Product Labeling: Medication Guide Requirements*, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (requiring Medication Guides for products that are deemed to pose significant public health concern) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at

odds with the agency's regulations."); FDA, *Final Rule, Labeling & Prescription Drug Advertising; Content & Format for Labeling of Human Prescription Drugs*, 44 Fed. Reg. 37,434, 37,437 (Jun. 26, 1979) ("It is not the intent of the FDA to influence the civil tort liability of the manufacturer . . .")).

Recently, however, the FDA has shifted its position radically and has argued that state litigation and federal regulation are antagonistic and mutually exclusive. The Solicitor General writing as amicus curiae in support of Petitioners asserts in this case that "[t]he federal government alone has responsibility to determine the appropriate remedy under the FDCA when it approved a product and later learned of misrepresentations that might have led it not to approve the product." (SG Br. at 32.)

This position overstates the FDA's enforcement authority and misconstrues the Michigan statute. After a drug is approved, "unless a case meets the *statutory* definition of fraud or misbranding or the high threshold for proving imminent hazard to the health of the public, FDA's regulatory and enforcement options generally lie at the ends of the spectrum of regulatory actions: do nothing or precipitate the voluntary withdrawal of the drug."[8] IOM Report at 157. FDA often declines to take formal action against a drug manufacturer who has engaged in conduct that might fall within the Michigan exemption and instead negotiates

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[8] The IOM Report notes that "[w]ithdrawals are almost always voluntary rather than mandated by FDA. According to its statute, FDA can institute recalls *only* for devices and baby formula." IOM Report at 157 n.1.

"softer remedies" with drug manufacturers. *Id.* Michigan does not impose remedies for a drug-maker's misrepresentations to the FDA; it merely vitiates the conclusive presumption of nonliability that the State itself conferred.

This Court should not defer to the FDA's position as articulated by the Solicitor General, because the Michigan statutory scheme is traditional legislation concerning state tort law, which FDA has long tolerated. *See* Resp. Br. at 10, 25-31. When an agency changes its position it is entitled to less deference. *See National Fed'n of Fed. Employees, Local 1309 v. Dep't of Interior*, 526 U.S. 86, 109-10 (1999); *see also Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 418 (1993) ("On the other hand, the consistency of an agency's position is a factor in assessing the weight that position is due. As we have stated: "An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view.") (citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446, n.30 (1987) (quoting *Watt v. Alaska*, 451 U.S. 259, 273 (1981))). "How much weight should be given to the agency's views in such a situation, and in particular where its shifts might have resulted from intervening and possibly erroneous judicial decisions and its current position from one of our own rulings, will depend on the facts of individual cases." *Good Samaritan Hosp.*, 508 U.S. at 418.

Instead, this Court should reaffirm the FDA's long-standing position that state tort claims such as Respondent's advance the FDCA's goal of consumer protection and the regulatory objective of prompt and effective warnings of serious health risks. And, this

Court should decline to extend *Buckman* to preempt application of the conclusive Michigan statutory exemption, which unlike *Buckman* does not create a state-law cause of action or inquiry into fraud on the FDA, but merely allows evidence of wrongdoing in the drug approval process to defeat Michigan's conclusive statutory presumption of non-liability for drug manufacturers.

A finding that the Michigan exemption is preempted would be inconsistent with Congress's intent in establishing and continuing the FDA's regulatory scheme. It also would undo the Michigan legislature's decision to reward drug-makers who comply with FDA's requirements by limiting their liability and to force those who do not to defend the safety of their products in court, consistent with the FDA's mandate. The FDA has stated that it is the latter state tort law claims that should be maintained: State tort claims should not be preempted if "the [drug's] sponsor withheld material information" from the FDA. 71 Fed. Reg. 3922, 3936 (2006). That position, restated so recently, recognizes that state tort liability complements the FDA in its mission. The FDA's job would be made only more difficult if the Court preempts the Michigan exemption and confers non-liability on drug-makers who withhold or misrepresent material information during the drug approval process.

CONCLUSION

For the foregoing reasons, Amicus urges this Court to affirm the decision of the Court of Appeals for the Second Circuit.

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In the Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICUS CURIAE*

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation.[1] The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the Nation's business community.

The Chamber is well situated to address the issues of federal preemption raised by this case. It has filed *amicus* briefs in many of the Court's leading preemption cases. Its members are engaged in commerce in each of the 50 States and are subject in varying degrees to a wide range of federal regulations, including comprehensive regulatory schemes for product approval such as the one administered by the Food and Drug Administration ("FDA"). Accordingly, its members often confront the interplay be-

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[1] The parties have each filed letters giving blanket consent to the filing of *amicus* briefs in this case. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

tween approval of a product by a federal agency and the potential for state common-law tort liability.

The Chamber's members are particularly concerned about the threat that courts will employ the vague and inconsistently applied "presumption against preemption" doctrine to elide actual conflicts between federal and state law, as the Second Circuit did below.[2] The Chamber is not only capable of offering a broader perspective on the role of that presumption than the parties may provide, but also is keenly interested in ensuring that the manner in which courts apply the presumption is consistent, clear, and rational.

INTRODUCTION AND SUMMARY OF ARGUMENT

By statute, Michigan law affords a pharmaceutical manufacturer complete immunity against a product liability action if it can demonstrate that the allegedly defective product at issue "received the FDA's approval and complied with the FDA's labeling and substantive requirements." Pet. App. 6a; see MICH. COMP. LAWS § 600.2946(5). This statutory immunity does not apply, however, if the plaintiff can

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[2] There is a split among the courts of appeals over whether the presumption against preemption applies to an analysis of conflict preemption. Compare *Wuebker* v. *Wilbur-Ellis Co.*, 418 F.3d 883, 887-889 (8th Cir. 2005) (applying presumption); *Oxygenated Fuels Ass'n* v. *Davis*, 331 F.3d 665, 673 (9th Cir. 2003) (same); *Green* v. *Fund Asset Mgmt., L.P.*, 245 F.3d 214, 223-224 (3d Cir. 2001) (same), with *Irving* v. *Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no presumption exists against preemption."); *Perry* v. *Mercedes Benz of N. Am., Inc.*, 957 F.2d 1257, 1261 (5th Cir. 1992) ("we do not begin with an assumption against *conflict* preemption").

demonstrate that the manufacturer, "at any time before the event that allegedly caused the injury," Pet. App. 6a, "[i]ntentionally withh[eld] from or misrepresent[ed] to the [FDA] information concerning the drug that is required to be submitted under the [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*], and [that] the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information [had been] accurately submitted." MICH. COMP. LAWS § 600.2946(5)(a). This case addresses whether this statutory exception to immunity "inevitably conflict[s]" with, and is impliedly preempted by, the FDA's responsibilities under federal law to approve pharmaceutical products and to "police fraud consistently with the Administration's judgment and objectives." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

In the course of determining that Michigan's statutory exception to immunity was not impliedly preempted, the court of appeals invoked a "presumption against federal preemption of state law." Pet. App. 18a. The court acknowledged that this Court had established in *Buckman* that no such presumption should apply when a State "invent[s] new causes of action premised on fraud against the FDA," *ibid.*, because "'[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied.'" *Ibid.* (quoting *Buckman*, 531 U.S. at 347) (emphasis removed). However, the Second Circuit distinguished this Court's refusal to invoke the presumption against preemption in *Buckman* on the ground that plaintiffs' "cause[s] of action" in this case, which survived Michigan's statutory immunity through operation of the exception, could not "rea-

sonably be characterized as a state's attempt to police fraud against the FDA." *Ibid.*

According to the court of appeals, Michigan's "legislative scheme" instead had "[t]he object * * * to regulate and restrict when victims could continue to recover under *preexisting* state products liability law." Pet. App. 18a (emphasis added). Because "[t]he Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to 'regulate matters of health and safety,'" the court of appeals reasoned, *id.* at 19a (quoting *Buckman*, 531 U.S. at 348; alterations omitted), the presumption—far from not applying at all—should instead "stand[] at its strongest." *Ibid.*[3]

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[3] There can be no question that the court of appeals' invocation of the presumption against preemption skewed its preemption analysis significantly. See Pet. App. 19a ("the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*"); *id.* at 19a n.6 ("This fact also substantially diminishes the persuasive effect of the federal law analysis made in *Garcia* [v. *Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004)], since the Sixth Circuit's holding in *Garcia* was based on the assumption that no presumption against preemption applied."); *id.* at 20a & n.7 (characterizing refusal to find that "Congress, without any explicit expression of intent * * * modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their customers" as "another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case"); *id.* at 24a (declining to find preemption in absence of "explicit[]" statement of Congress's intent) (quoting recitation of presumption in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996)); *id.* at 27a ("The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims.").

Petitioners' brief addresses in detail the language and purpose of the statutes and regulations that govern this case, and demonstrates why Michigan's statutory exception to immunity is preempted under well-established principles. Rather than duplicate those arguments here, we focus on a more broadly applicable and doctrinally significant aspect of the court of appeals' decision: that court's application of the so-called presumption against preemption. This element of the Second Circuit's holding was seriously flawed and has pernicious implications for a wide variety of other cases.

I. The time has come for this Court to clarify once and for all that the presumption against preemption simply does not apply to the analysis of whether state law conflicts with federal law. Although the Court has at times invoked the presumption when analyzing claims of *field* and *express* preemption (albeit inconsistently and controversially), it almost never has done so when addressing claims of *conflict* preemption. Moreover, in recent decisions involving conflict preemption, the Court's approach—in emphasizing ordinary principles of statutory interpretation and the inapplicability of any additional burdens prior to a finding of preemption—has cast significant doubt on whether the presumption has any relevance to a conflict preemption analysis.

Foundational and long-recognized principles of constitutional law and statutory construction fully justify the Court's consistent recent pattern of failing to apply the presumption when engaging in a conflict preemption analysis. As a preliminary matter, there is no textual basis in the Constitution for applying such a presumption in any circumstance, and the Court has never addressed the serious challenges

that have been levied against the free-form concept of "federalism concerns," which has been invoked to justify such a presumption. Regardless, conflict preemption is fundamentally different from field and express preemption—the strands of preemption doctrine in which the Court traditionally has applied the presumption—in that it does not require a court to infer Congress's preemptive intent. Determining whether there is an actual conflict between state and federal law instead requires a judicial interpretation of the substantive—as opposed to the preemptive—meaning of a statute. As this Court has made clear, such a substantive interpretation does not implicate the presumption. Once an actual conflict has been identified as a matter of substantive law, a finding of preemption follows inescapably from the Supremacy Clause.

II. Even if the presumption against preemption were ever applicable to a conflict preemption analysis, the lower court nonetheless would have erred in invoking that presumption here. As this Court held in *Buckman*, preemption of a state law that bears upon the inherently federal relationship between the FDA and a pharmaceutical manufacturer poses no threat to the historic primacy of state regulation in matters of health and safety.

There is no legitimate basis for distinguishing between a *cause of action* predicated on a finding of fraud on the FDA, as in *Buckman*, and a fraud-on-the-FDA *exception* to a generalized grant of statutory immunity from common law liability. Both necessitate a state court's independent inquiry into the adequacy and veracity of submissions to the FDA as a predicate requirement to establishing liability under state tort law. A state cannot so directly intrude into

the federal realm without losing any entitlement to the presumption against preemption that it might enjoy when regulating solely in those fields that have traditionally been the subject of state law.

In reaching the contrary conclusion, the court of appeals both mischaracterized the nature of the preemption at issue in this case and failed to apply the analysis mandated by this Court's precedents. This case does not involve the preemption of a state-law cause of action, as the court of appeals erroneously assumed; a finding of federal preemption would not itself preclude a plaintiff from asserting any state-law cause of action. Similarly, because the state law actually subject to preemption is merely the Michigan statutory exception to immunity, the court of appeals erred in focusing on the underlying state law causes of action, which it deemed "preexisting," "traditional," and "long-standing." Pet. App. 18a, 27a. The proper focus instead should have been on the statutory exception to immunity, which is of recent vintage and which necessarily bears upon an inherently federal relationship.

The court of appeals' conclusion that the presumption against preemption in this case "stands at its strongest," Pet. App. 19a, also rests on two other significant misinterpretations of this Court's precedents. First, the court of appeals sought to discern the Michigan legislature's motivation in enacting the immunity exception, although this Court has squarely rejected such reliance on a review of a legislature's motives. Second, the court of appeals ignored the primary lesson of *Buckman* with respect to the presumption against preemption: a state law that bears upon an inherently federal relationship is not entitled to the presumption because it does not

threaten the historic primacy of state regulation in matters of health and safety.

ARGUMENT

I. The Presumption Against Preemption Is Inapplicable To The Determination Whether State Law Actually Conflicts With Federal Law.

This Court's recent case law, as well as established principles of constitutional law and statutory construction, afford strong grounds for concluding that no presumption against preemption applies to the judicial determination of whether preemption is necessary because of an "actual conflict" between state law and valid federal law. *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 884 (2000).[4] Accordingly, the Court should end years of ambiguity and avoidance of this question and clarify that a court may not invoke the presumption when analyzing claims of conflict preemption.

A. This Court's recent decisions demonstrate that the presumption against preemption does not apply to a conflict preemption analysis.

As a general matter, the Court's adherence to the presumption against preemption—usually described

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[4] The Court's precedents establish that such an "actual conflict" exists (i) where it is impossible for a private party to comply with both state and federal requirements, or (ii) where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. See, *e.g.*, *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). There is no "legal wedge" between, and thus "no grounds * * * for attempting to distinguish," these two manifestations of actual conflict. *Geier*, 529 U.S. at 873–874.

as a requirement that Congress make its preemptive intent "clear and manifest" "[i]n areas of traditional state regulation," *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (internal quotation marks omitted); see also *Lohr*, 518 U.S. at 485—has been inconsistent and controversial. The Court's earliest Supremacy Clause cases made no mention of such a presumption, or of any analogous principle of special treatment for any state laws. See, *e.g.*, *Martin* v. *Hunter's Lessee*, 14 U.S. (1 Wheat.) 304, 343–344 (1816); *Ware* v. *Hylton*, 3 U.S. (3 Dall.) 199 (1796) (applying no presumption in case where treaty superseded state criminal law); see also *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 210 (1824) ("[I]t will be immaterial whether those laws were passed * * * in virtue of a power to regulate [the several States'] domestic trade and police. * * * [T]he acts of [the State] must yield to the law of Congress."). Indeed, during the first several decades of the 20th century the Court recognized a strong generalized presumption *in favor* of preemption. See Mary J. Davis, *Unmasking The Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 973–983 (2002).

It was not until 1947 that this Court first explicitly recognized the existence of an "assumption" of nonpreemption of the "historic police powers of the States," applicable when "Congress legislate[s] * * * in [a] field which the States have traditionally occupied." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 806–807 (1994). At issue in *Rice* was whether Congress had displaced all state law in a particular field, and the Court subsequently has at times applied this assumption of nonpreemption (also characterized as a "presumption against preemption") when analyzing

such claims of "field" preemption.[5] The Court also has applied the doctrine when interpreting express statutory preemption provisions, see, *e.g.*, *Bates*, 544 U.S. at 449; *Lohr*, 518 U.S. at 485; *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)—although the application of the presumption in this context has not been without controversy. See, *e.g.*, *Engine Mfrs. Ass'n* v. *S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004) (noting that "not all Members of this Court agree" on the "application" of the "presumption against pre-emption") (internal quotation marks omitted).[6]

By contrast, the Court almost without exception has avoided reliance on the presumption when addressing claims of conflict preemption.[7] It is true

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[5] See, *e.g.*, *English*, 496 U.S. at 79; *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985); but see *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 247 (1984) (field preemption analysis makes no mention of presumption).

[6] At least two current members of the Court reject the presumption's applicability in interpreting the scope of express preemption provisions. See, *e.g.*, *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part); *Cipollone*, 505 U.S. at 544 (Scalia, J., concurring in the judgment in part and dissenting in part); see also *Engine Mfrs. Ass'n*, 541 U.S. at 256.

[7] See, *e.g.*, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002); *Geier*, 529 U.S. 861; *United States* v. *Locke*, 529 U.S. 89 (2000); *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000); *Freightliner Corp.* v. *Myrick*, 514 U.S. 280 (1995); *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) (plurality); *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355 (1986); *Wis. Dep't of Indus., Labor & Human Relations* v. *Gould Inc.*, 475 U.S. 282 (1986); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202 (1985); *Brown* v. *Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491 (1984); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691 (1984).

that, in *Hillsborough County* and *California* v. *ARC American Corp.*, 490 U.S. 93 (1989), the Court did preface its conflict preemption analysis with a nod to the presumption. See 471 U.S. at 715–716; 490 U.S. at 101. In neither case, however, did the Court rely on the presumption in the actual conflict preemption analysis itself.[8] Moreover, as the Court later observed in its unanimous opinion in *Locke*, such mere "'prefatory'" references to the presumption in a decision do not establish that it actually was deemed applicable under the circumstance of that case. 529 U.S. at 90, 107–108 (citing *Ray* v. *Atl. Richfield Co.*, 435 U.S. 151, 157 (1978)).[9] Indeed, in *Crosby*, decided in 2000, the Court recognized that the applicability of the presumption in the conflict preemption context remained an open question. 530 U.S. at 374 n.8 ("We leave for another day a consideration in this context of a presumption against preemption.").

Although the Court has not addressed the issue directly, the analyses in several recent decisions have cast into significant doubt whether the presumption has any relevance in conflict preemption cases.

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[8] See *ARC Am. Corp.*, 490 U.S. at 105–106 (holding that "congressional purposes * * * provide no support for a finding that state [law is] pre-empted by federal law"); *Hillsborough County*, 471 U.S. at 722 ("In summary, given the findings of the District Court, the lack of any evidence in the record of a threat to the adequacy of the plasma supply, and the significance that we attach to the lack of a statement by the FDA, we conclude that [there is no conflict].") (internal quotation marks omitted).

[9] At least two post-*Rice* decisions addressing claims of both conflict and field preemption pointedly invoked the presumption only with reference to their field preemption analyses. See, *e.g.*, *Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 491 (1987); *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977).

The Court's most notable recent precedent bearing on this issue is *Geier*. In *Geier*, the Court held that federal law—a safety standard promulgated by the Department of Transportation under the National Traffic and Motor Vehicle Safety Act of 1966, in conjunction with that Act itself—preempted a state law tort action seeking to impose liability on an automobile manufacturer for failing to install an airbag. 529 U.S. at 881. A state law duty requiring automobile manufacturers to install airbags plausibly could be characterized as a core example of "state police power regulations," *Cipollone*, 505 U.S. at 518, "in a field which the States have traditionally occupied." *Lohr*, 518 U.S. at 485 (internal quotation marks omitted). Nevertheless, the majority in *Geier* never mentioned any presumption against preemption. See *Geier*, 529 U.S. at 906–907 (Stevens, J., dissenting) ("the Court simply ignores the presumption [against preemption], preferring instead to put the burden on petitioners to show that their tort claim would not frustrate [federal] purposes").

Instead, the *Geier* majority strongly implied that the presumption has no relevance to a conflict preemption analysis, emphasizing that the Court was applying "longstanding," "ordinary," and "experience-proved principles of conflict pre-emption." *Geier*, 529 U.S. at 874. Under these principles, preemption is necessary if there is a "demonstration of actual conflict" between state and federal law, with no additional "burden" weighing the scales either against or in favor of preemption. *Id.* at 874, 883. There were no grounds "for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case." *Id.* at 874. Indeed, the Court explicitly acknowledged and dismissed one of the dissent's

principal arguments in favor of invoking the presumption—the need for "a limiting principle that prevents federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes" (*id.* at 907) (Stevens, J., dissenting). See *id.* at 873–874.

Other recent decisions of the Court are consistent with *Geier*'s apparent rejection of the presumption in conflict preemption cases. For example, in *Locke*, the Court unanimously termed the presumption "artificial," declining to invoke it in analyzing whether federal law conflicted with state regulations in "an area where there has been a history of significant federal presence." 529 U.S. at 108. And, in *Sprietsma*, the Court made no mention of the presumption in holding that the Coast Guard's decision—pursuant to authority granted by federal law, see 46 U.S.C. § 4302—not to require propeller guards on boat motors did not conflict with a duty to install such guards sounding in state tort law. 537 U.S. at 64–68.[10] The Court's holding in *Sprietsma* turned on the failure of the Coast Guard to "convey an authoritative message of a federal policy against propeller guards"—a regulatory choice that the Court explicitly contrasted to "the decision of the Secretary of Transportation that was given pre-emptive effect in *Geier*." *Id.* at 67 (internal quotation marks and cita-

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[10] By contrast, the Court did reference the presumption in passing in its analysis (and rejection) of possible *field* preemption under the relevant federal statute. See *Sprietsma*, 537 U.S. at 69 (observing that the "structure and framework" of federal statute "do not convey a clear and manifest intent to * * * implicitly pre-empt all state common law relating to boat manufacture") (internal quotation marks and citation omitted).

tion omitted). Indeed, the Court suggested that, as in *Geier*, such an authoritative message, if it had been delivered, would have been "inconsistent with a tort verdict premised on a jury's finding that" a propeller guard was required, *ibid.*—speculation that hardly is consistent with the existence of a presumption weighing in favor of the survival of state law.[11]

B. Foundational and long-recognized principles preclude application of the presumption against preemption to a conflict preemption analysis.

The persistent refusal of the Court to invoke the presumption against preemption when analyzing conflict preemption issues in recent decisions is fully consistent with foundational and long-standing principles of constitutional law and statutory construction.

1. Notably, there is no basis in the text of the Constitution for a presumption against preemption in any circumstance. When Congress legislates within the scope of its enumerated powers, the Supremacy Clause renders these federal enactments "the supreme Law of the Land," U.S. CONST. art. VI, cl. 2, and "invalidates" "'interfer[ing]'" or "'contrary'" state law. *Hillsborough County*, 471 U.S. at 712 (quoting *Gibbons*, 22 U.S. at 211) (Marshall, C.J.). "[S]ince [the Court's] decision in *McCulloch* v. *Maryland*, [17 U.S. (4 Wheat.) 316, 427 (1819)], it has

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[11] In fact, harkening back to *Geier*'s reliance on "ordinary * * * principles of conflict pre-emption," 529 U.S. at 874, the *Sprietsma* Court pointedly characterized preemption as the *automatic* outcome of a direct conflict between a federal regulation and a state common law claim. See *Sprietsma*, 537 U.S. at 65 ("Of course * * * pre-emption would occur.").

been settled that state law that conflicts with federal law is without effect." *Cipollone*, 505 U.S. at 516 (internal quotation marks omitted).

Against the backdrop of this well-established framework rooted in the text of the Constitution, the Court has characterized the presumption against preemption as justified by "federalism concerns." *Lohr*, 518 U.S. at 485. It provides "assurance that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones*, 430 U.S. at 525 (internal quotation marks and citation omitted); see also *Geier*, 529 U.S. at 907 (Stevens, J., dissenting) (presumption is necessary to allow "the structural safeguards inherent in the normal operation of the legislative process [to] operate to defend state interests from undue infringement").

But this justification is not universally recognized even in the express preemption context. See, *e.g.*, *Cipollone*, 505 U.S. at 544 (Scalia, J.) ("Under the Supremacy Clause, [the Court's] job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly, but in accordance with their apparent meaning.") (citation omitted). More generally, the Supremacy Clause would itself appear to have resolved the invoked "federalism concerns" by establishing an unambiguous and bright-line constitutional rule for how federal and state law are to relate. Indeed, the Court has reiterated that "[u]nder the Supremacy Clause * * * the relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder* v. *Casey*, 487 U.S. 131, 138

(1988) (internal quotation marks omitted); see also *De Canas* v. *Bica*, 424 U.S. 351, 357 (1976) ("even state regulation designed to protect vital state interests must give way to paramount federal legislation").[12] Accordingly, as Professor Viet Dinh has argued, the Court's "systematic[] favor[ing]" of "one result over another" in analyzing preemption questions "risk[s] an illegitimate expansion of the judicial function" by "disrupt[ing] the constitutional division of power between federal and state governments, rewrit[ing] the laws enacted by Congress, or both." Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000).

As a matter of constitutional history, moreover, there is "no significant support * * * for the conclusion that the [F]ramers intended any * * * presumption to be read into [the Supremacy Clause]." Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. DAVIS L. REV. 1, 30 (2001). This is unsurprising given that the Framers' specific intention in designing the Supremacy Clause was "to remedy one of the chief defects in the Articles of Confederation by instructing courts to resolve state-federal conflicts in favor of federal law." David Sloss, *Constitutional Remedies for Statutory Violations*, 89 IOWA

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[12] Indeed, to the extent that the federalism justification for the presumption rests on emanations from the Tenth Amendment, it would appear to be at odds with the decision last Term in *Watters* v. *Wachovia Bank, N.A.*, 127 S. Ct. 1559 (2007), in which the Court squarely held that the Tenth Amendment "is not implicated" in the preemption analysis because "'if a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States.'" *Id.* at 1573 (quoting *New York* v. *United States*, 505 U.S. 144, 156 (1992)).

L. REV. 355, 402 (2004). Recent historical research suggests that this intention was built into the Supremacy Clause itself: the Framers would have understood the Supremacy Clause's *non obstante* clause—"any thing in the Constitution or Laws of any State to the contrary notwithstanding"—as *rejecting* "a general presumption that federal law does not contradict state law." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 293 (2000); see *id.* at 238–244, 254–260.

2. Despite these unresolved challenges to the presumption's theoretical foundations, the Court's decisions indicate that its invocation may be justified when a court must *infer* Congress's preemptive intent or purpose. See *Smiley* v. *Citibank (S.D.), N.A.*, 517 U.S. 735, 744 (1996) (presumption applicable in determining "whether a statute is pre-emptive").

Both express and field preemption analyses may require such an inference in the first instance. Express preemption analysis generally involves judicial interpretation of "explicit statutory language," *English*, 496 U.S. at 79, to determine whether it supplies an "express statement of pre-emptive intent," *Geier*, 529 U.S. at 884, and to "identify the domain" that Congress "intended" to invalidate by that statement. *Lohr*, 518 U.S. at 484–485 (internal quotation marks omitted).[13] Likewise, courts in field preemption cases look for support in the "substantive provisions of the

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[13] In such cases, the presumption affords a rule for construing the express preemption provision. See, *e.g.*, *Cipollone*, 505 U.S. at 518 ("we must construe these provisions in light of the presumption against * * * pre-emption"); *Bates*, 544 U.S. at 449 (presumption against preemption imposes "duty" on court "to accept the reading" of statutory preemption provisions "that disfavors preemption").

legislation," *Cipollone*, 505 U.S. at 517 (internal quotation marks omitted), for the inference that "Congress intends that federal law occupy a given field." *ARC Am. Corp.*, 490 U.S. at 100.[14]

As the Court has explained, however, "conflict pre-emption is different." *Geier*, 529 U.S. at 884. Conflict preemption does not turn on a judicial inference of Congress's preemptive intent; indeed, an actual conflict resulting in preemption may be found "[w]here Congress likely did not focus specifically on the matter." *Lohr*, 518 U.S. at 504 (Breyer, J.). Rather, conflict preemption turns "on the identification," based on "clear evidence," "of 'actual conflict'" between federal and state law. *Geier*, 529 U.S. at 884–885 (quoting *English*, 496 U.S. at 78–79).[15]

The existence of an "actual conflict" is a "question of the substantive (as opposed to preemptive) *meaning* of a statute"—an inquiry that, as the Court has explained, "does not bring into play" the presumption against preemption. *Smiley*, 517 U.S. at 744.[16] Application of a presumption against preemp-

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[14] See also *Hillsborough County*, 471 U.S. at 714 ("The question whether the regulation of an entire field has been reserved by the Federal Government is, essentially, a question of ascertaining the intent underlying the federal scheme.").

[15] See also *Ouellette*, 479 U.S. at 491 (distinguishing judicial "inference" of preemption, which courts should not undertake "lightly," from situation presenting "actual[] conflict[]") (internal quotation marks omitted).

[16] See also *Brown*, 468 U.S. at 503 ("[w]here, as here, the issue is one of an *asserted substantive conflict* with a federal enactment, then the relative importance to the State of its own law is not material") (emphasis added; internal quotation marks and alterations omitted); *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (holding that principles of con-

tion rooted in "structural safeguards" of federalism, *Geier*, 529 U.S. at 907 (Stevens, J., dissenting), would be particularly inappropriate when courts interpret Congress's substantive enactments because "Congress's chosen level of deference to state interests will be reflected in the language that Congress enacts." Nelson, 86 VA. L. REV. at 302. Applying the presumption would be "to give the * * * safeguards * * * a kind of double weight." *Id.* at 300. Accordingly, in a number of cases presenting issues of conflict preemption, this Court instead has applied its standard interpretive methods to arrive at broad constructions of substantive statutory meaning.[17]

Thus, a court's interpretation of the substantive meaning of statutory language must not be "confuse[d]" with a court's distinct inference as to whether, and to what extent, Congress intended to legislate preemptively. *Smiley*, 517 U.S. at 744. Since it is only with respect to the latter that the presumption against preemption can mandate congressional clarity—and because the latter may only be at issue in the express- and field- preemption contexts—there is no warrant for invoking the presumption to analyze whether state and federal law are in actual conflict.

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flict preemption are "not inapplicable * * * simply because [state law at issue] is a matter of special concern to the States").

[17] See, *e.g.*, *Watters*, 127 S. Ct. at 1567 ("We have 'interpreted grants of both enumerated and incidental 'powers' to national banks as grants of authority not normally limited by, but rather ordinarily pre-empting, contrary state law.'") (quoting *Barnett Bank of Marion Cty., N. A.* v. *Nelson*, 517 U.S. 25, 32 (1996)); *Allied-Bruce Terminix Cos.* v. *Dobson*, 513 U.S. 265, 275 (1995) (adopting "broad interpretation" of substantive language determining coverage of Section 2 of the Arbitration Act despite preemptive effect on conflicting state law).

3. Of course, once an actual conflict has been identified as a matter of substantive law, the Supremacy Clause requires the "nullifi[cation]" of the contrary state law, *Hillsborough County*, 471 U.S. at 713, no matter how "clearly within [the] State's acknowledged power" the law is, *Felder*, 487 U.S. at 138 (internal quotation marks omitted). See *Geier*, 529 U.S. at 873; *Irving*, 136 F.3d at 769; *Perry*, 957 F.2d at 1261-1262. Indeed, "[a] holding of federal exclusion of state law [at that point] is inescapable and requires no inquiry into congressional design." *Fla. Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142–143 (1963).

* * * * *

There is no basis in this Court's precedents, foundational principles of constitutional law, or the structure of our federal system for a court to invoke a presumption against preemption when analyzing a claim of conflict preemption. Straightforward application of the Supremacy Clause, by contrast, facilitates the realization of Congress's objectives and affords private actors—particularly in regulated fields—an important measure of legal certainty and predictability.[18] The "day" has come for the Court to "consider[]" the presumption in the conflict preemption context, *Crosby*, 530 U.S. at 374 n.8, and to hold that the presumption has no applicability there.

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[18] *See Geier*, 529 U.S. at 874 (noting the "legal uncertainty," and consequent "inevitable systemwide costs," imposed by an unnecessarily "complicated" preemption analysis); cf. *Cent. Bank* v. *First Interstate Bank*, 511 U.S. 164, 188 (1994) (noting "undesirab[ility]" of judicial "decisions made on an ad hoc basis, offering little predictive value") (internal quotation marks omitted).

II. The Presumption Against Preemption Would Not Apply In This Case Even Were It Ever To Apply To A Conflict Preemption Analysis.

Even were the presumption against preemption ever to apply in analyzing the question whether state and federal law are in actual conflict, but see Part I, *supra*, that presumption would nonetheless be inapplicable in this case. Rather than involving an area in which the States have long regulated, the state law at issue in this case is of recent vintage and plainly intrudes upon the inherently federal regulation of pharmaceutical companies by the FDA. Thus, the application of the presumption against preemption here would be unwarranted and could have undesirable consequences in a wide variety of situations.

A. The Michigan immunity exception trenches on an inherently federal relationship.

Because the state law at issue here necessarily intrudes on the inherently federal regulation of pharmaceuticals, under this Court's precedents the presumption against preemption should not apply.

1. Although this Court has not clearly delineated the circumstances in which the presumption against preemption may be invoked in a preemption analysis, the guidance that the Court has provided demonstrates that no such presumption is warranted here.

First, it is clear under this Court's precedents that the presumption is concerned primarily with "state police power regulations," *Cipollone*, 505 U.S. at 518, a category that in certain circumstances may

include "state-law causes of action." *Lohr*, 518 U.S. at 485; see also *Cipollone*, 505 U.S. at 523 (invoking presumption in determining whether "common-law claims" are preempted).

Second, even where there is such a regulatory state law at issue, the presumption applies only if the "area" in which the state law "regulates," *Locke*, 529 U.S. at 108, is one that "'the States have traditionally occupied.'" *Buckman*, 531 U.S. at 347 (quoting *Rice*, 331 U.S. at 230); see also *ARC Am. Corp.*, 490 U.S. at 101 (describing "presumption against finding pre-emption of state law in areas traditionally regulated by the States"). In particular, the presumption against preemption does not apply "when the State regulates in an area where there has been a history of significant federal presence." *Locke*, 529 U.S. at 108.

As the Court emphasized in *Buckman*, there is no presumption against preemption—and state law cannot be characterized as regulating in "a field which the States have traditionally occupied"—when a state law also can be characterized as "[p]olicing fraud against federal agencies." 531 U.S. at 347 (internal quotation marks omitted). This is so because "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Ibid.* (citing *Boyle* v. *United Techs. Corp.*, 487 U.S. 500, 504–505 (1988)); see also *id.* at 347–348 ("petitioner's dealings with the FDA were prompted by [federal law], and the very subject matter of petitioner's

statements were dictated by that [federal law's] provisions").[19]

The Court in *Buckman* thus focused on the *nature* of the relationship between a federal agency and a regulated entity—a relationship completely defined by "federal enactments" that constituted "a critical element in [plaintiffs'] case." 531 U.S. at 353.[20] Preemption of state law that "bear[s] upon" a relationship of such a federal nature, *Locke*, 529 U.S. at 108, poses no threat to "the historic primacy of state regulation of matters of health and safety" and, accordingly, does not warrant the presumption. *Buckman*, 531 U.S. at 348 (internal quotation marks omitted).

2. This case is not materially distinguishable from *Buckman* for purposes of determining whether a presumption against preemption should apply. The Michigan immunity exception relies on a showing that, like the cause of action at issue in *Buckman*, facially implicates the substance and propriety of the manufacturer's relationship with the FDA. See MICH. COMP. LAWS § 600.2946(5). There is no basis

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[19] Applying principles of conflict preemption, the Court determined in *Buckman* that federal law preempted state law tort claims alleging (i) that a defendant consulting company had "made fraudulent representations to the [FDA] in the course of obtaining approval" to market a medical device and (ii) that "such representations were at least a but for cause" of the plaintiffs' injuries. 531 U.S. at 343 (internal quotation marks omitted).

[20] Cf. *Chicago & Nw. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 317–318 (1981) ("in deciding whether any conflict is present, a court's concern is necessarily with the *nature of the activities which the States have sought to regulate*, rather than on the method of regulation adopted") (emphasis added; internal quotation marks omitted).

for arguing that the nature of the relationship between the manufacturer of a new drug and the FDA is any less "inherently federal in character" than the relationship between a medical device manufacturer (or its consultant) and the FDA in *Buckman*. 531 U.S. at 347. Rather, as petitioner has amply demonstrated, see Pet. Br. 3–11, federal law (i) "sets forth a comprehensive scheme" for determining if an applicant's new drug is entitled to FDA approval and specifying what the terms of that approval will be, *Buckman*, 531 U.S. at 348, and (ii) accords the FDA the same authorities to "detect[], deter[], and punish[] false statements made during" the approval process that this Court recognized in *Buckman*. *Id.* at 349. Accordingly, as in *Buckman*, there can be no question that federal law "prompted" "petitioner[s'] dealings with the FDA," and that "the very subject matter of petitioner[s'] statements [to the agency] were dictated by" the "provisions" of federal law. *Id.* at 347–348.

Nor is there any relevant basis for distinguishing a cause of action predicated on a finding of fraud on the FDA, as in *Buckman*, from the fraud-on-the-FDA exception to a generalized grant of statutory immunity from common law liability that is at issue here. As the Sixth Circuit has noted, the difference between the two forms of state regulation is "immaterial." *Garcia* v. *Wyeth-Ayerst Labs.*, 385 F.3d 961, 965–966 (6th Cir. 2004). Both create a predicate requirement to establishing liability under state tort law that directly and manifestly turns on a state court's independent inquiry into the adequacy and veracity of submissions to the FDA.

There can be no doubt that such a requirement "bear[s] upon," *Locke*, 529 U.S. at 108, a relationship

that is "inherently federal in character." *Buckman*, 531 U.S. at 347. To "bear" means, *inter alia*, "to relate or have relevance" or "to exert influence or force." MERRIAM-WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 191 (1986); see also, *e.g.*, *Allen-Bradley Local No. 1111* v. *Wis. Employment Relations Bd.*, 315 U.S. 740, 749 (1942) ("ha[s] an impact on"); *Boyle*, 487 U.S. at 506 ("implicate[s]"). That the relationship between the manufacturer and the FDA is mentioned on the very face of the statutory provision demonstrates conclusively that this standard is satisfied here.

Moreover, if, as here, the FDA has approved an allegedly defective drug and the drug and its labeling complied with that approval at the time of distribution, plaintiffs asserting product liability claims under Michigan law *must* allege fraud on the FDA for their cases to go forward; otherwise, their claims cannot survive under the statutory immunity provision. See MICH. COMP. LAWS § 600.2946(5). For such plaintiffs, the immunity exception renders "the existence of the[] federal enactments * * * a critical element in their case," which was the defining characteristic of the claims asserted in *Buckman* for purposes of the overall preemption analysis. 531 U.S. at 353; cf. *Grable & Sons Metal Prods., Inc.* v. *Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005) (noting federal interest in "claims recognized under state law that nonetheless turn on substantial questions of federal law").

Indeed, by hinging liability on Michigan's independent evaluation of the relationship between the FDA and the defendant pharmaceutical manufacturer, the immunity exception actually transforms the duty of such manufacturers to comply with FDA

new drug approval requirements—a duty that is entirely the creation of federal law—into a matter directly subject to concurrent regulation under state tort law. But as the *Buckman* Court recognized, such regulation necessarily presents the possibility that a state judge or jury will conclude that FDA approval of a drug was fraudulently induced, even where the FDA has drawn no such conclusion, or, indeed, has arrived at a contrary conclusion. 531 U.S. at 350. There can be no presumption against preemption when the state casts the "shadow of [its] tort regime[]" over a federal regulatory scheme. *Ibid.*

Thus, a state cannot conduct such a direct intrusion into the federal realm without losing any entitlement to the presumption against preemption that it might enjoy when it regulates solely in those fields that it has "traditionally occupied." *Buckman*, 531 U.S. at 347.

B. The court of appeals mischaracterized the nature of the preemption at issue in this case and did not apply the analysis mandated by this Court's precedents.

In determining that the issue presented by this case warranted invocation of a presumption against preemption, the Second Circuit purported simply to be following the precedents of this Court. See Pet. App. 18a–19a (citing to *Buckman* and *Lohr*). The rationale underlying the court of appeals' approach, however, misinterprets and directly contradicts a number of this Court's precedents, and the approach—if allowed to stand—would work a dramatic and improper expansion of the circumstances triggering the presumption.

1. As a preliminary matter, the court of appeals inaccurately characterized the preemption issue, citing the proposition that "'Congress does not cavalierly pre-empt state-law *causes of action*.'" Pet. App. 18a (quoting *Lohr*, 518 U.S. at 485) (emphasis added).[21] But this case does not involve the preemption by federal law of any state-law cause of action; rather, as the court of appeals seemed at one point to recognize, at issue is whether federal law impliedly preempts a statutory exception to *immunity* from liability. See Pet. App. 27a ("we conclude that the Michigan immunity exception is not prohibited through preemption"); see also *Garcia*, 385 F.3d at 966 ("*Buckman* prohibits a plaintiff from invoking the *exceptions* on the basis of state court findings of fraud on the FDA.") (emphasis added and removed).

Plaintiffs' product liability claims sound in Michigan's traditional common law of tort, not in any cause of action created by the immunity exception itself. See Pet. App. 18a ("[MICH. COMP. LAWS

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[21] See also Pet. App. 20a & n.7 ("were we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers"); *id.* at 3a ("Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as 'a critical component of the States' traditional ability to protect the health and safety of their citizens.'") (quoting *Cipollone*, 505 U.S. at 544) (Blackmun, J.); *id.* at 27a ("Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system."); *ibid.* ("The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims.").

§ 600.2946(5)] did not invent new causes of action premised on fraud against the FDA."). A finding that federal law preempts the immunity exception would result in plaintiffs' claims being extinguished (assuming severability, see *Garcia*, 385 F.3d at 967); but it would be *state law*—the statutory immunity shorn of the exception—that would be responsible, not federal law. Accordingly, federal preemption in the case at bar would itself preclude no plaintiff from asserting a state law cause of action. Indeed, a finding of preemption would impose no restrictions on the power of the Michigan legislature to repeal the statutory immunity to product liability suits that it has granted drug manufacturers, thereby potentially allowing such suits to go forward under traditional state law causes of action.[22] That in and of itself precludes the conclusion of the court of appeals that the presumption "stands at its strongest" here, Pet. App. 19a. See *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Dabit*, 547 U.S. 71, 87 (2006) (holding "that presumption carries less force" where federal law "does not actually pre-empt any state cause of action").

The Second Circuit's confusion as to the nature of the preemption at issue in this case also explains its misguided reliance on the observation that "the cause of action (which survives the changes made by [MICH. COMP. LAWS] § 2946(5)) cannot reasonably be characterized as a state's attempt to police fraud against the FDA." Pet. App. 18a. Nothing in *Buckman* suggests that the presumption-against-preemption inquiry turns on the characterization of the underlying state law cause of action, as opposed

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[22] Other forms of preemption might still be applicable in that instance, however.

to the characterization of the state law that actually is subject to preemption. In *Buckman*, because the state law at issue happened to be a cause of action, the characterization of that cause of action was relevant. In this case, however, the state law subject to preemption is the exception to statutory immunity, so the characterization of that immunity exception is what matters. As we demonstrated above (at 26-27), since the immunity exception clearly bears upon an inherently federal relationship, there should be no presumption against preemption here.

2. The court of appeals ultimately concluded that the presumption against preemption "stands at its strongest" in this case because "[t]he Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to regulate matters of health and safety." Pet. App. 19a (internal quotation marks and alterations omitted). That reasoning, too, is flawed for at least two reasons.

First, the court of appeals sought to discern the Michigan legislature's motivation in enacting the immunity exception. See Pet. App. 19a (evaluating legislature's "desire"); see also *id.* at 19a n.5 (finding "no evidence that the goal of preventing or punishing fraud against the FDA in any way motivated Michigan legislators to enact the statutory framework in question"). This Court, however, has squarely rejected reliance on this sort of review of a legislature's motivations in analyzing preemption issues. As the Court recognized over 35 years ago, it would be "aberrational" to allow "state law [to] frustrate the operation of federal law as long as the state legislature in passing its law had some purpose in mind other than one of frustration." *Perez* v. *Campbell*, 402 U.S. 637, 651-652 (1971); see also, *e.g.*, *Gade*, 505 U.S. at

105 (plurality) ("[i]n assessing the impact of a state law on the federal scheme, we have refused to rely solely on the legislature's professed purpose").

As the Court's precedents recognize, the Second Circuit's motive-based approach is unwise because, among other reasons, it would make the applicability of the presumption against preemption hinge on the state legislature's unilateral characterization of state law—a characterization that state lawmakers could manipulate easily. See *Perez*, 402 U.S. at 652 (rejecting "doctrine" that "would enable state legislatures to nullify nearly all unwanted federal legislation by simply publishing a legislative committee report articulating some state interest or policy"). Nor is there any support in *Locke* or *Buckman* for the proposition that whether state law bears upon an inherently federal relationship turns on the motivation of state lawmakers.

Second, the court of appeals ignored *Buckman*'s primary lesson in applying the presumption against preemption: state law that bears upon an inherently federal relationship cannot threaten "the historic primacy of state regulation of matters of health and safety." *Buckman*, 531 U.S. at 348 (internal quotation marks omitted).

Both the fraud-on-the-FDA cause of action at issue in *Buckman* and the fraud-on-the-FDA immunity exception at issue here establish the terms of liability under state tort law, and thus both can be characterized as implicating "matters of health and safety." *Lohr*, 518 U.S. at 485; see also *Geier*, 529 U.S. at 894 (Stevens, J., dissenting) (describing "provision of tort remedies to compensate for personal injuries" as type of state law that is "within the scope of the States' historic police powers").

But state regulation implicating matters of health and safety is entitled to the presumption against preemption *only* when it also can be characterized as falling within a "field" that "the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (internal quotation marks omitted); see also *Locke*, 529 U.S. at 107; *Geier*, 529 U.S. at 907 (Stevens, J., dissenting).[23] Such a characterization is impossible here given the direct intrusion on an inherently federal relationship. See Part II.A.2, *supra*. Indeed, as with the fraud-on-the-FDA cause of action at issue in *Buckman*, the immunity exception, which turns on a demonstration of fraud on a federal agency, necessarily cannot have predated the creation of that federal agency by federal law. See *Buckman*, 531 U.S. at 353 ("the fraud claims exist solely by virtue of the FDCA disclosure requirements").

As a practical matter, the court of appeals' approach, if allowed to stand, would permit States to circumvent *Buckman*'s limits on statutory causes of action that implicate inherently federal relationships by establishing, and then fine-tuning through myriad exceptions, statutory immunities to traditional state common law causes of action. Perversely, by encouraging accretion of immunities and exceptions to those immunities, such an approach in practice would inevitably result in complex state regulatory schemes that sweep broadly and disrupt a wide swath of traditional common law claims in order to

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[23] Cf. *Felder*, 487 U.S. at 138 (no mention of presumption against preemption in finding preemption of state rule of judicial procedure that conflicted with objectives of federal law, despite Court's acknowledgment of "the general and unassailable proposition * * * that States may establish the rules of procedure governing litigation in their own courts").

achieve limited regulatory goals. A simple rule that precludes invocation of the presumption against preemption whenever state law directly and manifestly bears upon an inherently federal relationship is both more consistent with this Court's precedents and far more rational. Such a rule will leave the States ample leeway to pursue their regulatory objectives.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC AND PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the Second Circuit defied this Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee* that "[s]tate-law fraud-on-the-FDA claims inevitably conflict" with federal law, 531 U.S. 341, 350 (2001), by holding that state-law claims which depend on proof of fraud on the FDA do *not* conflict with federal law.

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STATEMENT OF INTEREST[1]

The Generic Pharmaceutical Association ("GPhA") is a non-profit, voluntary association comprised of more than 140 manufacturers and distributors in the generic pharmaceutical industry, which accounts for more than 63 percent of prescriptions dispensed in the United States each year. GPhA's members provide American consumers with safe and cost-effective medicines that are bioequivalent to, and have the same therapeutic value as, their brand-name counterparts. These products significantly improve the public's health and welfare while cutting annual healthcare costs by billions of dollars.

GPhA's members—and the millions of Americans who depend on safe, affordable generic medicines—have a strong interest in ensuring that the U.S. Food and Drug Administration ("FDA") is positioned to evaluate all new pharmaceutical products efficiently and, where appropriate, promptly approve those products for commercial marketing. Despite the existence of an expedited pathway for new generic drug products, *see* 21 U.S.C. §§ 355 *et seq.* (the "Hatch-Waxman Act"), FDA's review process remains time-consuming and expensive, and the Agency

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[1] Letters of consent from both parties have been filed with the Clerk of the Court. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel for a party authored any part of this brief and that neither such counsel, nor any party, nor any person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

currently faces an unprecedented backlog of pending generic drug applications. *See, e.g.*, Steven Reinberg, *FDA Struggles to Keep Pace With Requests for Generics*, HEALTH DAY, Oct. 4, 2007 ("Despite improved handling of generic drug applications ... FDA has a backlog of more than 1,300 [generic] drugs awaiting approval.").

The Second Circuit's decision threatens to exacerbate that backlog and increase healthcare costs by authorizing state-law claims that pharmaceutical manufacturers defrauded FDA—even if FDA itself has made no such determination. If the appellate court's decision stands, generic and brand-name applicants alike will seek to stave off future claims of fraud the only way they can: by flooding FDA with superfluous documentation that, as this Court recognized in *Buckman Co. v. Plaintiffs' Legal Committee*, "the [Agency] neither wants nor needs." 531 U.S. 341, 351 (2001). That "deluge," *id.*, inevitably will cause further delays in FDA's already-burdened approval process, stifle competition, reduce the flow of safe, effective, and affordable pharmaceutical products to the market, and increase costs for both GPhA's members and the millions of Americans who depend on their products.

At bottom, the Second Circuit's decision in this case blasts a gaping hole in *Buckman*'s holding that federal law precludes such interference with FDA's statutory prerogatives and with the comprehensive statutory framework Congress designed to speed the approval of new drugs. GPhA's 140 members have an obvious interest in seeing this Court restore the integrity of that regime, and respectfully ask this Court to reverse the appellate court's judgment.

SUMMARY OF THE ARGUMENT

Seven years ago, this Court held without dissent that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law," because such "claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and "dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the [Food Drug and Cosmetic Act ("FDCA")]." *Buckman*, 531 U.S. at 348, 350.

That ought to be the beginning and end of this case. Plaintiffs here are asserting they were injured by Rezulin®, an FDA-approved drug that defendants lawfully marketed in the United States until they voluntarily withdrew it in March 2000. In order for plaintiffs to maintain their state-law claims—which include fraud, negligence, and misrepresentation, *see* Pet. App. 336a-37a, 343a-45a, 353a-54a—Michigan law expressly requires them not only to prove every element of each asserted claim, *but also* that defendants defrauded FDA by withholding or misrepresenting information they were required to submit to the Agency under specifically enumerated provisions of the FDCA, *and* that FDA would not have approved or maintained its approval of Rezulin® if defendants had complied with those specifically enumerated provisions of the FDCA. *See* MICH. COMP. LAWS § 600.2946(5)(a) (2007) (citing 21 U.S.C. §§ 301-21, 331-43-2, 344-46a, 347-53, 355-60, 360b-76, 378-95).

Buckman squarely held that federal law preempts state-law claims predicated on allegations that a

manufacturer defrauded FDA; Michigan law specifically requires plaintiffs to prove that defendants defrauded FDA in order to prevail; under *Buckman*, plaintiffs' claims are preempted.

The Second Circuit, however, attempted to distinguish *Buckman* on the ground that in that case, "proof of fraud against the FDA [wa]s *alone sufficient* to impose liability," Pet. App. 20a (emphasis in original), while in this case, proof of fraud against FDA merely would permit "pre-existing common law claims [to] survive." Pet. App. 21a. That assertion is both factually inaccurate and legally irrelevant.

It is factually inaccurate, because the alleged fraud on the FDA in *Buckman* merely served as the predicate false representation in a common-law fraudulent misrepresentation action, and that cause of action in turn required (among other things) proof of injury and proximate cause. *See In re Orthopedic Bone Screw Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998), *rev'd sub nom. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (explaining that plaintiffs' claim of fraud on the FDA "track[s] the elements of a common law cause of action for fraudulent misrepresentation"). The Second Circuit thus flatly erred in asserting that "proof of fraud against the FDA [wa]s *alone sufficient* to impose liability" in *Buckman*. Pet. App. 20a (emphasis in original). It was not.

Indeed, if anything, the Michigan statute at issue in this case conflicts even more directly with federal law than the common-law claims at issue in *Buckman*. After all, the Michigan statute at issue here *expressly conditions* plaintiffs' common-law

claims on proof that defendants defrauded FDA in the course of making certain FDCA-mandated disclosures, while the common-law fraud claims in *Buckman* *merely happened* to be premised on allegations that the defendants in that case defrauded FDA in the course of making certain FDCA-mandated disclosures.

But even if the appellate court were right about the nature of the claims in *Buckman*, its putative distinction of those claims is legally "immaterial"—as the Sixth Circuit held when it addressed this very issue. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004). Whether proof of fraud on the FDA is "*alone sufficient* to impose liability," Pet. App. 20a (emphasis in original), or instead serves as a statutory prerequisite to the maintenance of "pre-existing common law claims," *id.* 21a, claims that *depend* on proof of fraud on the FDA necessarily impinge upon FDA's comprehensive authority to "detect[], deter[], and punish[] false statements made during [the] approval process[]," *Buckman*, 531 U.S. at 349, and impose unwarranted burdens on the Agency, the industry it regulates, and ultimately, the consuming public. *Id.* at 350-51.

Contrary to the Second Circuit's assertions, those concerns apply with no less force here than in *Buckman*, and allowing these claims to proceed would have a particularly severe impact on the generic pharmaceutical industry—which depends on an expedited review and approval process that Congress established to speed the entry of generic drugs into the market. *See* 21 U.S.C. §§ 355 *et seq.* Continued pursuit of the claims at issue here thus would conflict with federal law no less than the

common-law claims this Court held to be preempted in *Buckman*. Accordingly, this Court should reverse the judgment.

ARGUMENT

The Second Circuit Defied This Court's Holding In *Buckman* That "State-Law Fraud-On-The-FDA Claims Inevitably Conflict" With Federal Law, By Holding That State-Law Claims Which Depend On Proof Of Fraud On The FDA Do *Not* Conflict With Federal Law.

The Second Circuit erred by holding that state-law claims which depend on proof of fraud on the FDA do not conflict with federal law and thus are not preempted. Indeed, that holding defies this Court's decision in *Buckman*, which expressly declared that "state-law fraud-on-the-FDA claims inevitably conflict with" federal law and "are therefore impliedly pre-empted." 531 U.S. at 348, 350. That decision controls here and requires dismissal of plaintiffs' claims. Plaintiffs are free to assert their claims that defendants defrauded FDA by lodging a complaint with the Agency, but *Buckman* unambiguously precludes them from litigating such claims in court.

The Second Circuit, however, asserted that *Buckman* does not control this case because the Michigan statute at issue here (in alleged contrast to the plaintiffs' claims in *Buckman*) does "not invent new causes of action premised on fraud against the FDA," Pet. App. 18a, but instead authorizes plaintiffs to "assert[] claims that sound in traditional state tort law," *id.* at 19a. *See also id.* at 20a ("[A]ll of the claims ... in this case are premised on traditional duties between a product manufacturer

and Michigan consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency.").

But that simply is not so. The *Buckman* plaintiffs did not assert some "new cause[] of action premised on" claims that the defendants in that case violated a "newly-concocted duty" they owed to FDA. Instead, they brought a plain-vanilla fraudulent misrepresentation claim that merely happened to proceed from allegations that the defendants' intentionally false representations to FDA resulted in their injuries. *See In re Orthopedic Bone Screw Liab. Litig.*, 159 F.3d at 821-22 (detailing plaintiffs' allegations of fraud and explaining that their claim "track[s] the elements of a common law cause of action for fraudulent misrepresentation: (1) a representation of fact, opinion, intention or law; (2) knowledge of its falsity; (3) an intent to induce reliance; (4) justifiable reliance; and (5) resulting injury") (citing RESTATEMENT (SECOND) OF TORTS §§ 525 *et seq.*).

That, of course, is why the Third Circuit's decision in *Buckman* went on to consider whether the plaintiffs' "complaints ... state[d] a claim for fraudulent misrepresentation," *see id.* at 826-29, and eventually concluded that "what we know about tort law generally makes us unwilling to say that all of the plaintiffs' claims will fail." *Id.* at 826 (quoting RESTATEMENT (SECOND) OF TORTS § 310 for the proposition that in certain circumstances, "[a]n actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by ... third person in reliance upon the truth of the representation")).

If anything, then, it is the Michigan statute at issue in this case—and not the plaintiffs' common-law claims of fraudulent misrepresentation in *Buckman*—that depends on "a newly-concocted duty between a manufacturer and a federal agency." Pet. App. at 20a. After all, the Michigan statute permits traditional state-law claims to proceed *only* if the defendant-manufacturer withheld or misrepresented information it was required to submit to FDA under the "federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395." MICH. COMP. LAWS § 600.2946(5)(a).

The Michigan statute's express reference to the FDCA's disclosure provisions refutes the appellate court's suggestion that the duties at issue here somehow predate the federal regulatory scheme. *Cf.* Pet. App. at 18a, 19a-20a. A statute that expressly conditions liability on proof that a defendant committed fraud in connection with specific federally mandated disclosures obviously postdates the federal scheme and renders "the existence of these federal enactments ... a critical element in [plaintiffs'] case." *Buckman*, 531 U.S. at 353. Regardless of whether plaintiffs' claims sound in fraud, negligence, products liability, or something else entirely, the Michigan statute at issue here unambiguously requires plaintiffs not only to prove each element of every asserted claim, *but also* that defendants defrauded FDA in the course of making certain specific FDCA-mandated disclosures regarding Rezulin®, *and* that FDA would not have approved or maintained its approval of Rezulin® had it not been defrauded. MICH. COMP. LAWS § 600.2946(5)(a).

The Second Circuit nonetheless sought to evade that conclusion by asserting that the Michigan statute merely creates an optional affirmative defense without formally altering the elements of a traditional common-law cause of action. Pet. App. 24a ("[T]he Michigan law in question does no more than create a defense that drug makers may invoke, *if they so decide*, and ... it is not up to the plaintiff to prove fraud as an element of his or her claim.") (emphasis added) (citing *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 134 (Mich. 2003)); *see also id.* at 23a ("The existence of properly-obtained FDA approval becomes germane *only if a defendant company chooses to assert an affirmative defense.*") (emphasis added).

With all due respect to the appellate court, that putative distinction both misses the point and turns a blind eye to the reality of pharmaceutical products-liability litigation. It misses the point, because as soon as the manufacturer of an FDA-approved product meets its razor-thin burden of showing that its product was FDA-approved (as plaintiffs necessarily concede Rezulin® was here), the burden unquestionably shifts to the plaintiff to prove that one of the statutory exceptions to § 600.2946(5) applies. *See, e.g., Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760, 767 (E.D. Mich. 2006). That, of course, helps explain why plaintiffs in this case affirmatively pleaded in their original complaints that defendants had defrauded FDA—that is, that the essential prerequisite to suit set forth in § 600.2946(5)(a) was satisfied in this case. *See, e.g.*, Pet App. 337a (¶¶ 22(F), 22(H), 23); *id.* 344a-45a (¶ 8); *id.* 353a-54a (¶¶ 7(F), 7(H), 8).

And it turns a blind eye to the reality of pharmaceutical products-liability litigation, because pharmaceutical defendants—no less than other sophisticated litigants—are not in the business of leaving dispositive statutory defenses on the cutting-room floor. That, too, helps explain why plaintiffs did not bother waiting for defendants to invoke § 600.2946(5), but affirmatively pleaded in their original complaints that the terms of § 600.2946(5)(a) were satisfied in this case. *See id.*

In sum, the claims at issue in this case are materially indistinguishable from the ones this Court held to be preempted in *Buckman*. As in *Buckman*, liability in this case depends on proof that defendants defrauded FDA in the course of making certain FDCA-mandated disclosures. And as in *Buckman*, permitting these claims to proceed would require a court (or jury) to place itself in FDA's shoes, determine whether FDA was defrauded, and if so, speculate as to whether FDA would have approved or maintained its approval of Rezulin® in the absence of such fraud. That is precisely the kind of inquiry that *Buckman* held would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" and thereby "exert an extraneous pull on the scheme established by Congress." 531 U.S. at 350, 353.

But even if the appellate court had identified a legally relevant distinction between the claims at issue in *Buckman* and the claims at issue here (which it did not), it provided no sound basis for concluding that the adverse practical consequences of permitting these claims to proceed would be less

significant here than in *Buckman*. After all, if states may condition the maintenance of products-liability and other common-law claims on proof that a manufacturer defrauded FDA in the course of fulfilling its FDCA-mandated disclosure duties, then manufacturers will take the only preventative course of action available to them: they will "submit a deluge of information [to FDA] that the Administration neither wants nor needs," *Buckman*, 531 U.S. at 351, and that "deluge" inevitably will disrupt FDA's ability to evaluate pending applications efficiently. *Id.*

The resulting burdens would take a particularly severe toll on generic drug applicants—and on the expedited approval process Congress established to speed the entry of generic drugs to the market. Indeed, more than two decades ago, Congress recognized the value of generic drug products by establishing a streamlined process designed to expedite FDA's review and approval of new generic drug applications and encourage manufacturers to develop safe, effective, and affordable generic medicines. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of titles 21, 35, and 42 U.S.C., and known as the "Hatch-Waxman Act" or "Hatch-Waxman"); *see also Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) (explaining that Hatch-Waxman was "[e]nacted to expedite the process by which companies gain approval to sell generic versions of already-approved brand-name drugs"); *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988) ("The purpose of [Hatch-Waxman] was to increase competition in the drug

industry by facilitating the approval of generic ... drugs.").

Congress has made a number of modifications to Hatch-Waxman over the years, *see, e.g.*, Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003), but its essential feature remains the same: while new drug applicants generally must submit volumes of clinical data and other information to show that a proposed new drug is safe and effective, "applicants who wish to manufacture generic versions [of a previously approved drug product] may instead complete an Abbreviated New Drug Application, or ANDA, which relies on the FDA's previous determination that the drug is safe and effective." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998); *see also* 21 U.S.C. § 355(j). Indeed, so long as the generic applicant demonstrates that its proposed generic drug product is bio- and therapeutically equivalent to a previously approved drug, its product may be approved by FDA without undergoing the "many years" of clinical trials branded manufacturers must conduct and without the "thousands of pages" of data branded manufacturers must submit to the Agency. *See* Br. of Petitioners at 5 & n.1.

Suffice it to say, Abbreviated New Drug Applications for generic pharmaceuticals are just that—*abbreviated*—and the expedited review process they make possible has been remarkably successful. As a direct result of Hatch-Waxman's streamlined application and approval process, generic medicines now account for more than 60 percent of all prescriptions dispensed in the United States (up

from 18.6 percent in 1984), but less than 20 percent of every dollar spent on prescription drugs. *See, e.g.*, Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993-94 (2007); *see also* Laura J. Robinson, *Analysis of Recent Proposals To Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 48 (2003) ("In effect, the Hatch-Waxman amendments created the modern generic drug industry.").

The Michigan statute at issue in this case nonetheless threatens to compromise Hatch-Waxman's expedited generic approval process by specifically authorizing plaintiffs to second-guess the sufficiency of disclosures made in connection with an abbreviated new drug application. *See* MICH. COMP. LAWS § 600.2946(5)(a) (identifying disclosures made pursuant to Hatch-Waxman as grounds for potential liability). If this Court authorizes such claims to proceed, the volume of information submitted with generic drug applications will increase dramatically as manufacturers seek to stave off future claims of liability, and the Agency's already-unmanageable backlog of more than 1,300 pending generic drug applications will swell even further as regulators begin to wade through those newly voluminous applications.

The net effect will be increased delays in the approval of generic drugs as FDA struggles to process expanded generic drug applications—reducing market competition between branded and generic products, increasing pharmaceutical costs, and ultimately depriving American consumers of prompt access to safe, effective, and affordable generic medicines. Permitting claims like the ones

at issue in this case to proceed thus would be demonstrably at odds with Congress's unambiguously expressed intent "'to make available more low cost generic drugs,'" *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (quoting H.R. Rep. No. 98-857 at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647), and this Court thus should reject the appellate court's efforts to evade *Buckman*.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment of the Second Circuit.

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Petitioners,

v.

KIMBERLY KENT, *ET AL.*,
Respondents.

On Writ of Certiorari to the United States Court Of Appeals for the Second Circuit

BRIEF FOR THE STATES OF KANSAS, *ET AL.* AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTIONS PRESENTED

Whether MICHIGAN COMP. LAWS § 600.2946(5)(a)—creating an exception to a state law statutory tort defense for drug manufacturers who have obtained approval of the federal Food and Drug Administration—is entitled to a presumption against preemption when challenged on the ground that it is impliedly preempted by federal law and, if so, whether the Petitioners have overcome that presumption?

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---

BRIEF FOR THE STATES OF KANSAS, *ET AL.* AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF THE *AMICI* STATES

The States have a paramount interest in their own tort laws, laws which are the result of the States' exercise of one of their most traditional police powers. Indeed, there is no general federal common law of torts, but there are 50 state tort systems. Even when federal law involves or implicates tort claims, federal law typically borrows and adopts state tort law. *See, e.g.*, 28 U.S.C. § 1346(b) (making the United States liable for the negligent torts of its employees "under circumstances where the United States, if a private person, would be liable to the claimant *in accordance with the law of the place where the act or omission*

occurred.") (emphasis added); *see also Molzof v. United States*, 502 U.S. 301, 305 (1992) ("the extent of the United States' liability under the FTCA is generally determined by reference to state law").

Tort law is one of the States' most traditional prerogatives, long exercised as a general State police power. Indeed, the common law of torts itself goes back centuries and, in this country, the development of the common law primarily has occurred in the state court systems.

Some states rely upon noncompliance with FDA requirements in defining the limits of tort liability in certain cases. Michigan does so by making noncompliance an exception to a general tort defense for manufacturers that have obtained FDA approval. MICH. COMP. LAWS § 600.2946(5), (5)(a). Other states rely upon noncompliance in another way, as an exception to a statutory bar on punitive damages claims that would otherwise apply to drug manufacturers that have obtained FDA approval. *See, e.g.*, ARIZ. REV. STAT. § 12-701; N.J. STAT. ANN. § 2A:58C-5C; N.D. CENT. CODE § 32-03.2-11(6), 7(a); OHIO REV. CODE ANN. § 2307.80(C); OR. REV. STAT. ANN. § 30.927; UTAH CODE ANN. § 78-18-2.

Several states accord a rebuttable presumption of nondefective design or of adequate warnings to FDA or other government approval, though not always with a noncompliance exception. *See, e.g.*, COLO. REV. STAT. § 13-21-403(1); IND. CODE ANN. § 34-20-5-1; KAN. STAT. ANN. § 60-3304(a); KY. REV. STAT. ANN. § 411.310(2); N.J. STAT. ANN. § 2A:58C-4; TENN. CODE ANN. § 29-28-104; TEX. CIV. PRAC. & REM. CODE § 82.007; UTAH CODE ANN. § 78-15-6(3).

Thus, many states have a direct interest in the question whether the Michigan noncompliance exception can be enforced. And, in any event, *all* the States have a substantial interest in the fundamental tort and preemption questions the case raises. *See, e.g.*, Catherine M. Sharkey, abstract for *The Fraud Caveat To Agency Preemption*, Nw. U. L. Rev., Vol. 102, No. 2, 2007, *available at* http://ssrn.com/abstract=1020722 (the *Warner-Lambert* case "raises a narrow doctrinal issue, but one that hits a raw federalism nerve, with correspondingly wide reverberations in products liability preemption jurisprudence").

Importantly, as the Second Circuit recognized and Petitioners and their *amici* agree, this case implicates once again the question in what circumstances a "presumption against preemption" applies to claims of federal preemption. The presumption is a first principle of great importance to the States, going to the very heart of federalism.

STATEMENT

1. Respondents, Michigan residents, sued Warner-Lambert Company LLC and Pfizer, Inc., in Michigan state court, asserting common law tort claims in connection with the Petitioners' product Rezulin, a drug marketed and sold for the treatment of Type-2 diabetes. The federal Food and Drug Administration (FDA) approved Rezulin in 1997. After it was documented that Rezulin caused adverse liver-related effects, Petitioners agreed to alter Rezulin labeling on several occasions between 1997 and 1999. In March 2000, Petitioners withdrew Rezulin from the market.

2. Respondents' tort claims included breach of implied and express warranties, negligence, negligent misrepresentation, negligence per se, fraud, defective design, defective manufacturing, and loss of consortium. A Michigan statute provides a general defense to drug manufacturers when the FDA has approved the drug in question. MICH. COMP. LAWS § 600.2946(5). However, the Michigan statute further provides that the defense does not apply if a drug manufacturer withheld from or misrepresented to the FDA information required to be submitted in obtaining FDA approval and such information would have affected the FDA's decision. *Id.* at § 600.2946(5)(a). This "noncompliance" exception is the provision at issue here.

3. Petitioners removed the case to federal court. Later, this case and others were consolidated as multidistrict litigation in the Southern District of New York. The District Court dismissed the case, holding that federal law preempted the exception in the Michigan statute. The court relied on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in which this Court held that a state could not impose liability for "fraud on the FDA" with respect to a medical device that the FDA had approved. Further, the District Court relied on *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), which held that *Buckman* required preemption of the Michigan exception.

4. The Second Circuit reversed, concluding that *Buckman* did not require preemption of the Michigan exception for several reasons: first, *Buckman* is distinguishable from this case, because it involved a state law "fraud" claim premised solely and directly

on the defendant allegedly committing fraud on the FDA; second, a "presumption against preemption" applies here, because tort law is at the very core of traditional state police powers; and third, the Michigan statute is a defense to products liability claims, not an element of a plaintiff's claim.

SUMMARY OF THE ARGUMENT

1. At a constitutional minimum, a presumption against preemption generally applies in "implied" preemption cases involving one of the States' most traditional police powers, such as tort law. That presumption has special force when there is a convergence of three important factors, as in this case: (a) the area of law allegedly preempted is one at the core of traditional state police powers; (b) the area of law—tort law—is not one in which there is or has been a significant federal presence; and (c) the relevant federal statutes are lacking in any express congressional declaration of intent to preempt traditional state police powers.

The Court has recognized several reasons for a presumption in these and other circumstances. First, only such a presumption will adequately protect the federalism structure inherent in the constitutional design. Second, a presumption permits judges to avoid unnecessary and problematic guessing as to the preemptive "intent" of Congress when the relevant federal laws are silent regarding preemption. Third, a presumption against preemption reserves for Congress the primary power to determine when state law is preempted.

Contrary to some suggestions in *amici* briefs supporting the Petitioners, there is not a basis for distinguishing among types of implied preemption for

purposes of applying the presumption. Instead, as this Court has recognized and Petitioners acknowledge, there is not a rigid line between "conflict" and "field" preemption. Pet. Br. at 21 and n.9 (citing and quoting cases). Rather, these labels are different ways to describe what is the same—a potential conflict between federal and state law in a situation where Congress has not expressly preempted state law. *See, e.g.*, Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 263 (2000).

2. A presumption, when rebuttable, as in this context, is a starting point, not a final conclusion. Sometimes the presumption will be overcome, for example when state law inevitably and necessarily conflicts with federal law, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), or when there is a logical inconsistency between federal and state law, or it is literally impossible to comply with both federal and state law. But, with all due respect, the argument which the Petitioners and their *amici* should be making in this case is not that there is no presumption against preemption, but that it is overcome here. Instead, they miss the mark when they seek to rewrite this Court's jurisprudence by arguing that no presumption applies in this case, or indeed in any case.

3. A presumption is particularly appropriate here because the States are free to structure their tort law as they wish, without federal constitutional or statutory constraints. A State may choose to provide a defense to drug or medical device manufacturers from tort liability when FDA approval has been obtained (as Michigan did here), but as a matter of federalism and constitutional principle, the States

are not required to adopt that view. The greater power—to give drug manufacturers a defense—necessarily encompasses the lesser power to impose conditions on the defense.

The flaw in Petitioners' argument is the apparent assumption that FDA approval immunizes them from state tort liability as a matter of federal law, so that Michigan's noncompliance exception interferes with that purported federal immunity. But that is the wrong premise—FDA approval gives Petitioners no defense to or immunity from state tort claims other than that which a particular state may choose to grant as a matter of legislative grace.

Thus, if a state chooses to create a defense not recognized at common law, it also may impose conditions on or limits to that defense. So long as the States do not effectively impose a tort law duty based on FDA processes and decisions, *see Buckman*, federal law does not impliedly preempt traditional state products liability law.

The practical effect of finding preemption here may be that States decline to accord FDA approval of new drugs any special legal significance in tort cases. Indeed, the States may choose not to create a defense for drug manufacturers under any circumstances. If the greater power—to provide manufacturers a defense from liability—does not include the lesser (to impose conditions on such a defense), then some States that currently have statutory defenses may well decide to alter or repeal them. Others are less likely to adopt such defenses at all.

4. Finally, the Michigan noncompliance exception does not affect the evidence generally admissible in traditional state law products liability actions.

Evidence of a manufacturer's knowledge of the risks its product poses, including what the manufacturer disclosed or failed to disclose to government regulators, generally is relevant and admissible in traditional products liability actions alleging negligence, design defect, and failure to warn.

The common law rule is that obtaining government approval or complying with government regulation is relevant evidence but not, in and of itself, a tort defense and does not create immunity. Michigan, by statute, departed from that rule, creating a defense in cases where drug manufacturers have obtained FDA approval. Michigan's noncompliance exception to that defense, however, follows the common law tradition of not treating government approval as a complete defense to tort liability. Rather, the States have a strong interest in protecting their citizens from negligence, defectively designed products, and products with inadequate warnings.

Michigan's choice—as a matter of policy—to provide a statutory defense to drug manufacturers who have obtained FDA approval, while also creating an exception in cases where the defendant has not fully complied with regulators' requirements and expectations, does not affect or expand the evidence that typically would be relevant and admissible in state law products liability actions. Preempting Michigan's exception would not bar the admission of evidence regarding a manufacturer's knowledge of the risks its product poses.

Ultimately, the Michigan statute here no more conflicts with federal law nor frustrates federal purposes than does the unquestioned state common law tort rule that government approval of a product

is not a defense in and of itself. Consequently, this Court need not and should not read *Buckman* to require preemption of the Michigan exception. Rather, tort liability for negligence, defective design, and failure to warn involves one of the States' most traditional police power prerogatives, is not an area in which there is a history of significant federal presence, and Congress has not declared an intent to preempt such state tort law.

* * * * *

Concurrent and overlapping federal and state regulation of the same activities is an inherent feature of our constitutional design. The structure of the Constitution demands no less; indeed, the framers purposely created federalism. The States readily acknowledge that federal power is supreme within its sphere when properly exercised. But a presumption against preemption is a proper mechanism for giving effect to the constitutional design, particularly when one of the core state law police powers is at issue.

ARGUMENT

I. AT A CONSTITUTIONAL MINIMUM, A PRESUMPTION AGAINST PREEMPTION APPLIES WHEN FEDERAL LAW IS ALLEGED TO PREEMPT ONE OF THE STATES' MOST TRADITIONAL POLICE POWERS—TORT LAW, THERE IS NO HISTORY OF SIGNIFICANT FEDERAL PRESENCE, AND THERE IS NO CONGRESSIONAL EXPRESSION OF INTENT TO PREEMPT STATE LAW.

A. A Presumption Against Preemption Serves Important Constitutional Purposes In Cases Involving The Most Traditional State Powers.

1. This Court has said that "[i]n *all* pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (emphasis added) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005). Thus, "[w]ith rare exception, [the Court has] found preemption only when a federal statute commanded it, when a conflict between federal and state law precluded obedience to both sovereigns, or when a federal statute so completely occupied a field that it left no room for additional state regulation." *Watters v. Wachovia Bank, N.A.*, 550 U.S. ___, ___,

127 S. Ct. 1559, 1585-86 (2007) (Stevens, J., dissenting) (internal citations omitted).[1]

a. The States readily acknowledge that federal power is supreme within its sphere, as the Supremacy Clause of Article VI declares. And it is true that the Tenth Amendment, reserving to the States and the people powers not granted to the Federal Government, does not itself preclude preemption of state law when the Federal Government has properly exercised its powers under the Constitution.

That said, all preemption cases implicate federalism and respect for the constitutional role of the States as sovereign entities. *Cf. Alden v. Maine*, 527 U.S. 706, 713 (1999). Thus, "because the States' are independent sovereigns in our federal system, [the Court has] long presumed that Congress does not cavalierly pre-empt state law causes of action." *Lohr*, 518 U.S. at 485. Rather, "the fact that the [Tenth] Amendment was included in the Bill of Rights should nevertheless remind the Court that its [preemption] ruling affects the allocation of powers among sovereigns. Indeed, the reasons for adopting

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[1] The application of a presumption against preemption when interpreting federal statutes that expressly declare an intent to preempt some aspects of state law has been criticized. *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part); *Bates*, 544 U.S. at 457 (Thomas, J., joined by Scalia, J., concurring in the judgment in part and dissenting in part). But such criticism of a presumption in "express" preemption cases has been accompanied by calls for a narrow approach to "implied" preemption, with no suggestion that a presumption should not apply generally in "implied" preemption cases. *See, e.g., Bates*, 544 U.S. at 459.

that Amendment are precisely those that undergird the well-established presumption against preemption." *Watters*, 550 U.S. at ___, 127 S. Ct. at 1585 (Stevens, J., dissenting).

Because "[t]he purpose of Congress is the touchstone of pre-emption analysis," *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992), a presumption against preemption operates much like the "clear statement" rule that applies in the Tenth and Eleventh Amendment contexts. *See, e.g., Gregory v. Ashcroft*, 501 U.S. 452, 457-61 (1991) (discussing clear statement rule in the Tenth Amendment and preemption contexts); *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 55-56 (1996) (the clear statement rule in the immunity context "arises from a recognition of the important role played by the Eleventh Amendment and the broader principles that it reflects"); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 238-39 (1985); *Quern v. Jordan*, 440 U.S. 332, 345 (1979). A presumption is not a constitutional *bar* to federal preemption, but it does require Congress to be clear about its intent. Thus, a presumption reserves for Congress the primary role in deciding when federal statutes preempt traditional state law.

b. The justifications for a presumption against preemption are at their zenith in this case. Indeed, "implied" preemption is at best an ambiguous and uncertain doctrine. Accordingly, members of the Court regularly have warned against expansive notions of implied preemption, describing the "Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption," *Bates*, 544 U.S. at 459

(Thomas, J., joined by Scalia, J., concurring in the judgment in part and dissenting in part); *see also Camps Newfoundland/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting), and cautioning that implied preemption is not "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment).

Judicial caution is particularly proper here for three reasons. First, this case involves one of the States' most traditional police powers—tort law. "The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates*, 544 U.S. at 449.

Second, although this Court has indicated that a presumption "is not triggered when the State regulates in an area where there has been a history of significant federal presence," *United States v. Locke*, 529 U.S. 89, 108 (2000); *see also Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 88 (2006); *Buckman*, 531 U.S. at 347-48, that circumstance is not present here. The federal government does not have a history of regulating tort law, either generally or with respect to drugs.

The federal government for the better part of the twentieth century has played a role in regulating food and drug products, but it largely did so in conjunction with a widely-recognized choice by Congress not to

preempt traditional state tort law liability principles. That fact is driven home by the absence of any federal cause of action or remedies for those injured by harmful food and drugs subject to FDA regulation.

Policing fraud on federal agencies is neither the purpose, the goal, nor the effect of the Michigan statute, *cf. Buckman*, 531 U.S. at 347 ("Policing fraud against federal agencies" is not a state prerogative); instead, the Michigan statute regulates tort law liability rules and defenses. Establishing tort liability principles is one of the most traditional exercises of the States' general police powers.

Third, all parties and *amici* acknowledge that there is no express preemption provision applicable in this case. Thus, a finding of preemption in this case cannot rest on the "express intent" of Congress, further confirming the wisdom and propriety of applying a presumption against preemption.

2.a. Contrary to the suggestions of some *amici* in this case, there is no basis for this Court to distinguish between "conflict" and "field" preemption in applying a presumption against preemption. Conflict and field preemption are not separable and distinct concepts, neither theoretically nor practically, as this Court has recognized and Petitioners concede. *See, e.g., English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990) (the categories are not "rigidly distinct" and "field pre-emption may be understood as a species of conflict pre-emption"); *Gade*, 505 U.S. at 104 n.2 (1992) (plurality opinion) (recognizing that the Court could describe the situation presented as either one of "conflict" or "field" preemption); *id.* at 115-16 (Souter, J., dissenting) (acknowledging that conflict preemption

may in practical effect be the same as or similar to field preemption); Pet. Br. at 21 and n.9.

Rather, federal law "conflicts" with state law when federal law "occupies the field" in which a state law purports to operate. Vice versa, federal law always "occupies the field" to the extent it is in actual "conflict" with state law. Thus, "field" and "conflict" preemption are two sides of the same coin. The state sovereignty concerns that favor a presumption against preemption are equally strong no matter which label one attaches to the situation. *Cf. Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000) ("We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case.")

b. Contrary to the suggestion of Petitioners and their *amici*, applying a presumption against preemption broadly instead of narrowly in implied preemption cases *simplifies*, rather than complicates, the preemption analysis. A rule that a presumption against preemption applies in cases involving the most traditional of state police powers, no history of significant federal presence in the area, and no express congressional declaration of intent to preempt is relatively clear and simple. Thus, with all due respect, the Court's decisions indicating that the presumption generally applies are correct. *See, e.g., Lohr*, 518 U.S. at 485 ("In all pre-emption cases" a presumption against preemption applies.)

A presumption against preemption may be overcome by an inevitable conflict between federal and state law, logical inconsistency between the two, or the impossibility of complying with both. Even so,

the presumption applies, and proponents of preemption bear the heavy burden of persuading a court that a conflict requiring preemption inevitably and necessarily exists.

3. The States have a paramount interest in their own tort law. There is no general federal common law of torts, but there are 50 state tort systems. Indeed, when federal law involves or implicates tort claims, it typically borrows state tort law. *See, e.g.*, 28 U.S.C. § 1346(b) (making the United States liable for the negligent torts of its employees "under circumstances where the United States, if a private person, would be liable to the claimant *in accordance with the law of the place where the act or omission occurred.*") (emphasis added); *see also Molzof*, 502 U.S. at 305 ("the extent of the United States' liability under the FTCA is generally determined by reference to state law").

Tort law is one of the States' most traditional prerogatives, long exercised as a general State police power. This Court has upheld state tort law in the face of preemption claims even when there was a strong federal interest in the subject matter and a State imposed substantial *punishment* for noncompliance with state tort law requirements. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) (upholding $10 million state law punitive damage award involving a federally-regulated nuclear power plant).

There may be no area of public safety, health, and welfare regulation that is more a traditional province of the States than tort law. The Court has suggested that Congress may lack even the *power* to regulate certain matters where the States' sovereign interests

are strong and the federal interest is tenuous. *See, e.g, United States v. Lopez*, 514 U.S. 549, 561 n.3 (1995) (state primacy in criminal law generally), *United States v. Morrison*, 529 U.S. 598, 615-16 (2000) (overly expansive commerce power would improperly permit Congress to regulate traditional state domestic relations law).

The reasoning of such cases supports the principle that federal statutes that do not even purport to preempt state law should not be read to preempt implicitly one of the most traditional areas of state police power regulation—tort liability and remedies. "[F]ederalism canons like the *Rice* presumption [against preemption] in particular, are legitimate ways of giving effect to underenforced constitutional principles. Such canons also perform the important function of buttressing political and procedural checks on national power and, as a result, reduce the need to rely on substantive constitutional limitations." Ernest A. Young, *Federal Preemption and State Autonomy*, in FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 249, 265 (R. Epstein & M. Greve, eds. 2007).

The Court has "long presumed that state laws—particularly those such as the provision of tort remedies to compensate for personal injuries, that are within the scope of the States' historic police powers—are not to be pre-empted by a federal statute unless it is the clear and manifest purpose of Congress to do so." *Geier*, 529 U.S. at 894 (2000) (Stevens, J., dissenting, joined by Souter, J., Thomas, J., and Ginsburg, J.). "Because we are unlikely to jettison the post-New Deal interpretation of the Commerce Clause, it becomes both necessary and

legitimate for courts to formulate 'compensating adjustments' to protect the federal balance under modern circumstances." Young, *Federal Preemption*, at 266.

The Supremacy Clause is not a means for asking the federal judiciary to impose tort reform on the States. *Geier*, 529 U.S. at 894 (Stevens, J., dissenting). Applying a presumption against preemption—at least in cases that involve the most traditional areas of state police powers, no history of significant federal presence, and no express declaration by Congress of an intent to preempt traditional state law—respects the States' constitutional role as sovereigns. Lastly, a presumption respects the role of Congress in such matters as well: "[t]he signal virtues of this presumption are its placement of the power of preemption squarely in the hands of Congress, which is far more suited than the Judiciary to strike the appropriate federal/state balance (particularly in areas of traditional state regulation), and its requirement that Congress speak clearly when exercising that power." *Id.* 529 U.S. at 907 (Stevens, J., dissenting).

B. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), Does Not Control Here.

1. The *only* claim at issue in *Buckman* was a fraud claim, and it was against a consultant, not the product manufacturer. The Court's opinion is clear that traditional products liability claims such as negligence, design defect, and failure to warn were not at issue (and could not have been, given that the defendant was not the manufacturer). Thus, *Buckman* was an unusual and unique tort case, with

"fraud on the FDA" an essential element of the claim against a consultant who was the *sole* defendant.

In *Buckman*, "fraud on the FDA" was *the dog*; here, Michigan's noncompliance exception is *the tail*, not the dog, as the Second Circuit recognized. Respondents' causes of action under Michigan law are based "on traditional state tort law principles of the duty of care owed by" drug manufacturers, *Buckman*, 531 U.S. at 352, and "rely[] on traditional state tort law which had predated" the FDA's approval process. *Id.* at 353.

2. What distinguishes this case further from *Buckman* is that here Petitioners are seeking a defense or an immunity that neither the common law nor federal law recognizes. If a state, like Michigan, chooses to create a tort defense not recognized at common law, *see* Part II, *infra*, there is no apparent reason why that state cannot also set the terms and conditions of that defense, including any limits or exceptions to it. When a defense to state tort liability is a matter of legislative grace—a pure policy decision not dictated by either federal preemption or the common law—the greater power to create the defense necessarily includes the lesser power to set the terms and conditions of the defense.

Perhaps in some states the creation of such a defense may be challenged as violating state constitutional provisions, like those that require a remedy by due course of law or other guarantees, as in fact happened in Michigan with this very statute. *See Taylor v. Smithkline Beecham Corp.*, 658 N.W. 2d 127 (Mich. 2003). But that is a matter for state supreme courts to decide—a question of state law. *See, e.g.*, David Schuman, *The Right to a Remedy*, 65

TEMPLE L. REV. 1197 (1992). The FDA-related statutes do not contain any express preemption provision that grants *federal immunity* to drug manufacturers who obtain FDA approval. Nor is anyone claiming here that the FDA statutes preempt the States from making a policy decision to create a tort defense on the basis of FDA approval.

3. Read fairly and objectively, *Buckman* can be understood in at least two ways, so that both Petitioners and Respondents can find aspects of the opinion that support their positions in this case, just as the Sixth and Second Circuits did. But, at the end of the day, what tips the scale in favor of a narrower reading of *Buckman* is the fact that Respondents' claims here are typical and traditional state tort actions, unlike the *sole* claim and *unique* defendant in *Buckman*. Further unlike *Buckman*, the Michigan provision is an exception to a tort defense created as a matter of legislative policy, a defense not recognized at common law. The noncompliance exception itself follows the common law tradition and is a logical exception to the statutory defense.

The Michigan statute has neither the purpose nor the effect of regulating the FDA and those who make applications to the agency. Quite the contrary, the statute "implicat[es] federalism concerns and the historic primacy of state regulation of matters of health and safety." 531 U.S. at 348. The noncompliance exception follows the common law regarding products liability cases, as further explained below. Thus, the Michigan noncompliance provision fits comfortably within the scope of the States' traditional police power to define tort law within their borders.

II. MICHIGAN'S NONCOMPLIANCE PROVISION DOES NOT AFFECT THE EVIDENCE ADMISSIBLE IN STATE LAW PRODUCTS LIABILITY ACTIONS.

A. Tort law long has endorsed the rule that government approval of a product or compliance with government regulation generally does not create tort law immunity. *See, e.g.*, W. Page Keeton, *et al.*, PROSSER AND KEETON ON THE LAW OF TORTS, § 36, p. 233 (5th ed. 1984) ("Such a standard is no more than a minimum, and it does not necessarily preclude a finding that the actor was negligent in failing to take additional precautions"); *see also* RESTATEMENT (SECOND) OF TORTS § 288 C (1965).

Instead, "[u]nder the common law, the defendant's compliance with a statute is not in itself a defense to a negligence action." Dan B. Dobbs, THE LAW OF TORTS, § 373, p. 1033 (2000) (footnote omitted). Importantly for this case, "[t]he common law rule in products cases is the same—evidence of compliance with statute or regulation is relevant to judgments about the product's alleged design or warning defects and hence admissible but not by any means conclusive." *Id.* at 1033-34 (footnotes omitted).

One reason for the common law rule is that "[f]requently, regulations are intended to provide a floor or a minimum level of safety, not an optimal level or a ceiling on safety precautions." *Id.* at 1034. Another reason is that "even if legislatures and regulatory agencies are not 'captured' by the industries they regulate, statutes and regulations may reflect the heavy influence of the regulated industry as much as judicious concerns with safety." *Id.* Yet another reason is that "[m]ost federal law is

regulatory in nature; regulators are not likely to think through tort issues when they formulate rules that may be appropriate from an administrative viewpoint but not from a tort law viewpoint." *Id.* For these reasons and others, the common law does not treat government approval as creating a defense to, or immunity from, products liability actions.

B.1. The view that government approval is not conclusive regarding product safety and creates no tort immunity continues strongly to this day. Section 4 of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) provides as follows:

> § 4. Noncompliance and Compliance with Product Safety Statutes or Regulations
>
> In connection with liability for defective design or inadequate instructions or warnings:
>
> (a) a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and
>
> (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, *but such compliance does not preclude as a matter of law a finding of product defect.*

Emphasis added; *see also id.* § 6 (defining potential liability of prescription drug manufacturers for manufacturing defects, design defects, and inadequate warnings).

Several members of the Court recognized and discussed these very principles in an earlier preemption case, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000). The dissenting opinion in *Geier* made the explicit point that Honda's compliance with federal regulations regarding airbags in motor vehicles presumably would be admissible to respond to claims of negligence and defective design, but "would not provide Honda with a complete defense on the merits." 529 U.S. at 892 (Stevens, J., dissenting). The *Geier* dissent further recognized that evidence of compliance with regulatory standards "would presumably weigh against an award of punitive damages," *id.* at 893, but would not bar or preempt such an award under state tort law principles. *Id.* (citing *Silkwood v. Kerr-McGee Corp.*).

That discussion in *Geier* is an accurate description of the common law of torts generally, and no state but Michigan grants drug manufacturers a defense to all tort liability by virtue of obtaining FDA approval of a drug. Rather, in the "overwhelming majority of jurisdictions," RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 Reporters' Note, cmt. e, evidence of FDA approval would not be conclusive and would not create a complete defense to, or immunity from, tort claims.

B.2. Furthermore, there is no express preemption provision in the relevant FDA statutes. As one well-respected tort law scholar puts it, "[f]ood and drugs are regulated heavily, but with no obvious preemptive intent." Dobbs, THE LAW OF TORTS, § 373, p. 1033 (footnote omitted). Thus, FDA approval of a new drug does not preempt general state tort law, nor does it create a defense to liability as a matter of

federal law. Rather, unless and until Congress declares otherwise, the legal significance, if any, of evidence of FDA approval of a new drug in state law products liability actions is determined by the law of each state.

States need not and generally do not immunize drug manufacturers from potential state tort liability based on FDA approval. Instead, because traditional products liability theories include concepts such as negligence, defective design, and failure to warn, the question of what a manufacturer knew or should have known about the risks its product posed often is central to a plaintiff's case under state tort law. Evidence addressing that question may well include documents and other materials submitted to, or withheld from, government regulators.

Some states, such as Kansas for example, direct that evidence of government approval or compliance with government regulation creates a rebuttable presumption of nondefectiveness or adequate warnings. *See* KAN. STAT. ANN. § 60-3304(a). But, at the same time, such States generally are clear that any presumption is rebuttable; it remains open to plaintiffs to prove "that a reasonably prudent seller could and would have taken additional precautions." *Id.* Evidence of product risks of which a drug manufacturer knew or should have known will be admissible to rebut the effect of evidence regarding government approval.

In other words, evidence that drug manufacturers failed to disclose risks that an FDA-approved drug poses is relevant and admissible in state law products liability actions generally, FDA approval notwithstanding. And such evidence might well

include information and documents that were or were not provided to the FDA, both prior to and following the approval of the drug. Even without a noncompliance statutory provision, evidence of manufacturers' knowledge and disclosures—or lack thereof—is relevant in traditional products liability actions under state tort law, and generally admissible.[2]

Thus, Michigan's noncompliance exception does not affect the kind of evidence that is already relevant and admissible in products liability actions under state law generally. To put it another way, Michigan's exception embodies traditional common law tort principles.

That Michigan chose—as a matter of policy—to provide a statutory defense to drug manufacturers who have obtained FDA approval, while it at the same time created a noncompliance exception, results in no significant change, if any, in the evidence that typically would be relevant and admissible in products liability actions. The Michigan statute no more conflicts with federal law nor frustrates federal purposes than does the unquestioned common law rule that government approval of a product does not create tort immunity.

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[2] In any event, there is no bar to the States permitting or authorizing traditional products liability actions for damages, or even state law "fraud" claims, based on an FDA finding of fraud. In that instance, state law unquestionably "would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." *Buckman*, 531 U.S. at 354 (Stevens, J. joined by Thomas, J., concurring in the judgment).

As the Court stated many years ago in another preemption case, "[n]o doubt there is tension between the conclusion that [certain] regulation is the exclusive concern of the federal law and the conclusion that a state may nevertheless award damages based on its own law of liability." *Silkwood*, 464 U.S. at 256. A presumption against preemption is not a constitutional bar to federal preemption of state law when Congress clearly expresses an intent to preempt. But given the federalism that our Constitution created, a presumption is essential to respecting state sovereignty and inherent in our system, at least in cases involving (1) the most traditional areas of state police power, such as tort law, (2) no history of significant federal presence in such an area, and (3) no express declaration by Congress of its intent to preempt such traditional state tort law.

Importantly, a presumption permits the courts to leave the ultimate resolution of doubtful and unclear cases where such a determination belongs—in Congress. Only by reserving for Congress the primary role in preemption cases will "the right of the State courts to establish the [tort] liability of the persons involved in the normal way [be] maintained." *Silkwood*, 464 U.S. at 253 (internal citation omitted).

CONCLUSION

The Second Circuit correctly held that a presumption against preemption applies in this case and that federal law does not implicitly preempt Michigan's noncompliance exception to a statutory defense based on FDA approval of a drug. The judgment below should be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
AND PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES, COUNCIL OF STATE GOVERNMENTS, NATIONAL ASSOCIATION OF COUNTIES, AND INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION AS *AMICI CURIAE* SUPPORTING RESPONDENTS

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QUESTION PRESENTED

Whether federal regulation of drugs impliedly preempts application of the exception to a drug manufacturer's regulatory-compliance defense set forth in Mich. Comp. Laws § 600.2946(5), while leaving the defense itself intact.

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INTEREST OF THE *AMICI CURIAE*

Amici are organizations whose members include state, county, and municipal governments and officials throughout the United States.[1] *Amici* have a strong interest in this Court's preemption jurisprudence and in preserving state-law remedies that effectuate the States' historic responsibility to protect public health and safety. They thus share with the FDA a "core public health mission," U.S. Br. 24, which includes "protecting the public health by ensuring that . . . drugs are safe and effective." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-34 (2000).

The FDA disclaims any interest in policing fraud by drug companies. *See* U.S. Br. 24. *Amici*, by contrast, have a compelling interest in ensuring that persons like respondents have remedies for intentional torts resulting in injury and death, such as those allegedly committed by petitioners. *Amici* accordingly submits this brief to assist the Court in the resolution of this case.

SUMMARY OF ARGUMENT

1. Petitioners' attempt to expand the reach of *Buckman* to forbid any determination by a state court that could be construed as a finding that fraud was committed on the FDA should be rejected. Evidence that a manufacturer marketed a drug that it knew to be unreasonably toxic prior to seeking FDA

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[1] The parties have consented to the filing of this *amicus* brief and their consent letters have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity, other than *amici* and their members, has made a monetary contribution to the preparation or submission of this brief.

approval may well be evidence of "fraud on the FDA," but such evidence has unquestionably been admissible for decades in state products liability litigation. Acceptance of petitioners' argument would make FDA drug approval an absolute immunity to suit and would render remediless the victims of the worst class of tortfeasors—those that intentionally withhold evidence of a drug's toxicity in order to obtain FDA approval. Because Congress did not intend such a result, but rather recognizes that the FDA and the States share a "core public health mission," U.S. Br. 24, petitioners' preemption arguments should be rejected.

Affirmance of the judgment below is also supported by the strong presumption against preemption of state health laws. Such a presumption is particularly strong in this case, where preemption would eliminate respondents' only remedy for petitioners' alleged malfeasance. "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Because Michigan's statute is a classic exercise of state police power to protect public health, this case is not controlled by *Buckman*, which involved no exercise of state police power. Under this Court's precedents, the presumption against preemption has special force when the States and the Federal Government are pursuing common purposes.

Affirmance of the judgment below is also consistent with the common law tradition embodied in the Restatement (Third) of Torts: Product Liability (1998). The Restatement confirms that in the overwhelming majority of jurisdictions, compliance with product safety regulation is relevant to the question

of negligence. The Restatement goes much further, however. "When the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency" in question, "compliance with regulation is entitled to little or no weight." *Id.* § 4 cmt. e.

As the Restatement reflects, state courts adjudicating the liability of drug manufacturers have long admitted as proof of negligence evidence that the manufacturers have withheld material information from the FDA. Michigan, by incorporating regulatory noncompliance into its statutory scheme, is simply mirroring what many other state legislatures and courts have been doing for decades. In those States, as in Michigan, evidence of regulatory noncompliance is central to proof of a drug manufacturer's negligence.

2. While the FDA has mechanisms to police fraud, it apparently does not do so to protect the interests of the victims of fraud and did not do so here. Indeed, the FDA has made plain to this Court that when the FDA suspects "fraud on the FDA" it often "reaches a settlement with the applicant in which the applicant pays a fine or takes corrective action (such as changes in labeling) without admitting liability." U.S. Br. 24. The FDA also acknowledges that persons injured by toxic drugs have no private right of action under the FDCA. *Id.* at 4. Given the shared public health mission of FDA and the States, Congress did not intend to preempt traditional state-law remedies such as those asserted here.

Moreover, victims of "fraud on the FDA" are a congressional concern, and Congress has given the States the responsibility to act on that concern. The

FDA argues for a result that would use preemption principles to leave victims of the worst tortfeasors without any legal remedy. That outcome is contrary to Congress's consistent approach of allowing state tort remedies for persons harmed by medication known by the manufacturer to be toxic. The FDA may have discretion to barter away its interest in pursuing fraud against itself, but it cannot, consistent with Congress's intent, barter away the state-law remedies of the victims of such fraud. The judgment below should accordingly be affirmed.

ARGUMENT

Petitioners seek to expand the reach of *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), to forbid any determination by a state court that could also be construed as a finding that fraud was committed against the FDA. The implications of this argument are deeply disturbing because conduct that is evidence of products liability and "fraud on the FDA" has been relevant and admissible in tort litigation for decades.

If this Court accepts petitioners' argument, it will eliminate the only remedy available to victims of the worst class of tortfeasors—those that intentionally withhold from the FDA data on toxic side effects in order to obtain the agency's unwitting approval to market lethal drugs. If the allegations against Warner-Lambert are true, its marketing of Rezulin without full disclosure of its pre-application knowledge about the drug's liver toxicity is a textbook example of such gross malfeasance. *See* Resp. Br. 4–5. Petitioners nevertheless insist that Congress intended to immunize these tortfeasors where state liability is conditioned upon a state court finding that a manufacturer withheld material information from the

FDA, an inquiry that the FDA perceives to be within its exclusive federal province to consider.[2] It is clear that Congress did not intend to create the regulatory void that would result if petitioners prevail.

Amici fully agree with respondents' arguments for affirmance of the judgment below. This brief advances two related arguments: (1) the importance of the presumption against preemption of state health laws to this case, and (2) why a state court's evidentiary finding that a manufacturer withheld material information from the FDA is congruent with Congress's intent to preserve state tort remedies for harms caused by defective and dangerous drugs.

I. THE STRONG PRESUMPTION AGAINST PREEMPTION OF STATE HEALTH AND SAFETY LAWS SUPPORTS AFFIRMANCE.

States are "vested with the responsibility of protecting the health, safety, and welfare of [their] citizens," and have "great latitude" when carrying out that responsibility. *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 127 S. Ct. 1786, 1795–96 (2007). Accordingly, the Court has "long presumed that Congress does not cavalierly pre-empt state law causes of action," particularly in

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[2] The United States contends that "federal law precludes a state rule—whether as an element of a claim or of a defense—that turns on whether FDA would have denied approval or withdrawn it sooner if it had received accurate information." U.S. Br. 21. It also claims that "fraud on the FDA" cannot be a predicate for liability, noting the substantial overlap between the common-law duty relevant to the state proceeding and conduct characterized as "fraud on the FDA." *See* U.S. Br. 27–28 & n.8, 30. Although the Court need not address the issue as broadly as the United States suggests, the Court's opinion could well have ramifications for products liability litigation throughout the country.

"field[s] which the States have traditionally occupied." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The "presumption against the pre-emption of state police power regulations" is "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)).

The presumption against preemption reflects this Court's longstanding reluctance to interfere with the regulatory authority of the States in the absence of Congress's clear intent. *See Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) ("Where . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977))). The force of this principle is manifest here, where preemption will eliminate the only legal remedy for victims of intentional malfeasance. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

Because Michigan's statute is a classic exercise of state police power, the outcome in this case is not controlled by *Buckman*, which implicated no such exercise. *See* 531 U.S. at 348 (observing that no presumption against preemption applied to a stand-alone fraud-on-the-FDA claim, "in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health

and safety'" (quoting *Medtronic*, 518 U.S. at 485) (internal citation omitted)).

Thus, unlike the claim in *Buckman*, the Michigan statute is subject to a deferential analysis that presumes that Congress expected some degree of overlap between state and federal laws that share the common goal of protecting public health. *See* U.S. Br. 24; *cf. Silkwood*, 464 U.S. at 256 (recognizing the inherent overlap between federal safety regulation under the Atomic Energy Act and state tort law, but holding that "Congress intended to stand by both concepts and to tolerate whatever tension there was between them").

Indeed, this commonality militates towards a particularly robust presumption against preemption. Michigan, no less than the United States, has an interest in the goal of "ensur[ing] that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quoting 21 U.S.C. § 393(b)(2)). Under these circumstances, "[t]he presumption against federal pre-emption of a state statute designed to foster public health . . . has special force when it appears . . . that the two governments are pursuing 'common purposes.'" *Pharmaceutical Res. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (opinion of Stevens, J.) (quoting *New York State Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 421 (1973)).

A. Michigan's Statute Is an Exercise of Police Power to Protect Public Health and Safety, Not an Attempt to Regulate a "Strictly Federal Matter."

Michigan law provides the strongest state-law immunity for drug manufacturers in the nation—an

"absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval." *Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003) (construing Mich. Comp. Laws § 600.2946(5)). Drug manufacturers are subject to suit in Michigan only if FDA approval was based on inaccurate or incomplete information or bribery, such that if the truth was known the FDA would not have approved the product or would have removed it from the market. Mich. Comp. Laws § 600.2946(5)(a)–(b).

Michigan enacted section 600.2946(5) because it "was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs." *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 775 (N.J. 2007) (quoting *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 967 (6th Cir. 2004)).[3] According to Michigan's Senate Fiscal Agency, "the legislation was based [on] the perception of an 'explosion' in product liability litigation." Resp. Br. 29 n.8 (quoting Michigan Senate Fiscal Agency, SFA Bill Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at *1 (Jan. 11, 1996)). Such added costs for drug manufac-

[3] In this respect Michigan acted for the same reasons that the United States now represents to be the dual goals of the FDCA: "striking a balance between keeping unsafe products off the market and making efficacious products available to patients and doctors." U.S. Br. 17 n.3. *But see Brown & Williamson*, 529 U.S. at 133-34 (FDA's mission includes "protect[ing] the public health by ensuring that . . . drugs are safe and effective" (quoting 21 U.S.C. § 393(b)(2)); *see also id.* at 162 (Breyer, J., dissenting) ("[T]he [FDCA]'s basic purpose [is] the protection of public health.").

turers could have a direct effect on public health and safety.[4]

At the same time, the Michigan legislature recognized that there are instances in which a drug manufacturer's conduct negates the probative value of FDA approval. This recognition accords with a long tradition in state products liability law that is embodied in the Restatement (Third) of Torts: Products Liability (1998):

> § 4. Noncompliance and Compliance with Product Safety Statutes or Regulations
>
> In connection with liability for defective design or inadequate instructions or warnings:
>
> (a) a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and
>
> (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

Id. § 4; *see also* Restatement (Second) of Torts § 288B(1) (1965) ("The unexcused violation of the legis-

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[4] *See Rowe*, 917 A.2d at 774 (sponsors in the Michigan Senate recognized that "[c]onsumers . . . suffer when they are denied new products that would increase public safety or improve their quality of life. . . . [P]roduct liability litigation . . . has added substantially to the cost and unavailability of many goods and services." (quoting Mich. Sen. Fiscal Agency, *supra*, at *10)).

lative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself.").

The Restatement confirms that "[t]he overwhelming majority of jurisdictions hold that compliance with product safety regulation is relevant and admissible on the question of defectiveness, but is not necessarily controlling." Restatement (Third) of Torts: Prod. Liab. § 4 cmt. d Reporter's Note (1998). But "when the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product," the Restatement emphasizes that "compliance with regulation is entitled to little or no weight." *Id.* cmt. e. Regarding the liability of drug manufacturers for defective prescription drugs, the Restatement expressly provides that "[a] manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect." *Id.* § 6.

In essence, section 4 states that regulatory noncompliance, such as "the withholding of necessary and valid information from the agency that . . . approved the product," renders a drug defective, and section 6 makes the manufacturer of that drug liable to persons injured because of its regulatory noncompliance. Thus, state-law principles of regulatory noncompliance complement the federal mission by advancing the common governmental goal of protecting public health. *Compare* Restatement (Third) of Torts: Prod. Liab. § 6(b)(3) (a prescription drug is de-

fective if it "is not reasonably safe due to inadequate instructions or warnings") *with* 21 C.F.R. § 314.2 (2007) (the purpose of the FDA approval process is to "ensure the disapproval of drugs not shown to be safe and effective").

As the Restatement further confirms, state courts have long admitted evidence that drug manufacturers have withheld material information from the FDA as proof of negligence or negligence per se, inadequate warning, or to rebut a defendant's claim of regulatory-compliance immunity. *See, e.g.*, *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1179–80 (5th Cir. 1988) (holding that preemption applies if manufacturer marketed product in compliance with FDA reporting and warning requirements but remanding for inquiry as to "whether and what information the manufacturer withheld from the FDA, if any, and whether possession of this information would have materially altered the contents of the FDA's warning"); *Stanton v. Astra Pharm. Prods., Inc.*, 718 F.2d 553, 563–64 (3d Cir. 1983) (holding that a drug manufacturer's withholding of material information from the FDA was negligence per se under Pennsylvania law); *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 409 (Cal. Ct. App. 1967) (holding that "violation of the labeling and marketing provisions of the [FDCA] may be shown to establish negligence").[5] Such a "long his-

[5] *See also In re Medtronic, Inc., Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886, 896 (D. Minn. 2006) (holding that, because plaintiffs' claims that defendant withheld critical information from the FDA were "premised on violations of FDA requirements," those claims were not preempted); *Brown v. DePuy Spine, Inc.*, 22 Mass. L. Rptr. 425 (Mass. Super. 2007) (holding evidence of defendant's failure to disclose known risks to the FDA admissible for the purpose of supporting plaintiff's state law claim of negligence); *Mears v. Marshall*, 944 P.2d 984,

tory of tort litigation" in this area "adds force to the basic presumption against pre-emption." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449–50 (2005).

By incorporating regulatory noncompliance into the statutory scheme, Michigan effectuates the States' historic power to protect public health and safety. Because the purpose of the FDA's regulatory scheme is to "[f]acilitate the approval of drugs shown to be safe and effective" and to "ensure the disapproval of drugs not shown to be safe and effective," *see* 21 C.F.R. § 314.2, it stands to reason that noncompliance with those regulations is evidence that a drug is not safe. Therefore, Michigan's incorporation of regulatory noncompliance into its statute furthers the purpose of ensuring that prescription drugs are safe for its citizens' consumption.

Michigan is far from alone in employing the regulatory compliance doctrine as a source of evidence of negligence in products liability actions. Under Texas law, FDA approval of a drug creates "a rebuttable presumption" of non-liability, which the plaintiff can refute by showing that the defendant "withheld from or misrepresented . . . required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." Tex. Civ. Prac. & Rem. Code

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992 (Or. App. 1997) (holding that claims that defendant "withheld crucial information from the FDA during the initial PMA process" were admissible to support plaintiff's claims of negligence and strict liability); *Green v. Dolsky*, 685 A.2d 110, 117–18 (Pa. 1996) (holding, post-*Lohr*, that the MDA did not preempt claims that "mirror FDA requirements," including claims that defendant "provid[ed] FDA with false, fraudulent, incomplete testing results" and "false, fraudulent, incomplete adverse reaction of injury information").

Ann. § 82.007(b)(1).[6] Statutes in six States use the regulatory compliance doctrine to determine the availability of punitive damages, making evidence of noncompliance admissible to support punitive damages claims that would otherwise be barred by FDA approval.[7]

Six other States have enacted general products liability statutes that create a presumption that a product was not defective, or that a manufacturer was not negligent, if the manufacturer complied with all applicable federal regulations. *See* Ark. Code Ann. § 16-116-105(a); Colo. Rev. Stat. § 13-21-403(1)(b); Ind. Code § 34-20-5-1; Kan. Stat. Ann. § 60-3304(a); N.D. Cent. Code § 28-01.3-09; Tenn. Code

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[6] In 2007, a single-judge trial court ruled that this statute is preempted by the FDA under *Buckman*. *See Ledbetter v. Merck & Co.*, Nos. 2005-59499, 2005-58543, 2007 WL 1181991 (Tex. Dist. Ct. Apr. 19, 2007).

[7] *See* Ariz. Rev. Stat. § 12-701(B) (punitive damages available if defendant withheld or misrepresented "information known to be material and relevant to the harm which the plaintiff allegedly suffered"); N.J. Stat. Ann. § 2A:58C-5(c) (punitive damages available for withholding or misrepresentation of "information which was material and relevant to the harm in question"); N.D. Cent. Code § 32-03.2-11.7 (same); Ohio Rev. Code Ann. § 2307.80(C)(2) (punitive damages available for withholding "information known to be material and relevant to the harm that the claimant allegedly suffered"); Or. Rev. Stat. § 30.927(2) (same); Utah Code Ann. § 78-18-2(2) (same).

While the wording of Michigan's statute is unusual when compared to those quoted above, *see* Mich. Comp. Laws § 600.2946(5)(a) ("the drug would not have been approved or the [FDA] would have withdrawn approval for the drug"), it is clear that this difference is purely semantic and that the Michigan statute is directed at drug manufacturers that withhold or misrepresent evidence which is material to the plaintiff's tort claim. *Cf.* Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(1).

Ann. § 29-28-104. Statutes in two States provide that noncompliance with a relevant federal regulation creates a presumption that the product was defective or negligently manufactured. *See* Colo. Rev. Stat. § 13-21-403(2); Kan. Stat. Ann. § 60-3304(b).

The common law of numerous states relies upon the regulatory compliance doctrine as proof of negligence or negligence per se, inadequate warning, or to rebut a drug manufacturer's assertion of regulatory-compliance immunity. *See* discussion at 11–12 & n.5, *supra*.[8] Michigan's statute differs from these laws by granting manufacturers of FDA-approved drugs a *greater* measure of protection from liability: FDA approval creates an immunity from suit, save for the two enumerated exceptions, rather than a presumption that an approved drug is safe. *See Rowe*, 917 A.2d at 772 (presumption created by the Michigan statute is "conclusive," while that created

[8] Violation of any FDCA requirement has long been admissible evidence in state tort suits. *See, e.g., Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 733 (2d Cir. 1979) (failure to provide adequate warnings of known risks, in violation of the FDCA, was negligence per se under New York law); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 460–61 (4th Cir. 1960) (misbranding in violation of the FDCA was negligence per se under Virginia law); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981), *amended by* 532 F. Supp. 211 (E.D. Wis. 1981) (because the FDCA "is designed to protect a class of persons from a particular type of harm, a violation of the statute which results in that type of harm to someone in the protected class constitutes negligence per se" under Wisconsin law); *Batteast v. Wyeth Labs., Inc.*, 560 N.E.2d 315, 323 (Ill. 1990) (violation of FDA regulation may be considered prima facie evidence of negligence if plaintiff belongs to the class the regulation was meant to protect if injury had direct and proximate relation to the regulation); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 71 (Mass. 1985) ("[V]iolation of FDA requirements is evidence, but not conclusive evidence, of negligence.").

by comparable New Jersey statute is merely "rebuttable").

In these States, as in Michigan, evidence of regulatory noncompliance is central to proof of a drug manufacturer's negligence. Whatever other uses this evidence may have under federal law, a court adjudicating a state-law claim may consider whether evidence of a drug's toxicity was withheld from the FDA by the manufacturer for its own purposes. These state laws, like Michigan's statute, are founded on principles of fundamental fairness and the historic responsibility of the States to provide appropriate remedies for intentional torts.

B. Petitioners' Arguments Against Applying the Presumption Against Preemption Are Unpersuasive.

Amici agree with respondents' argument that *Buckman* does not control in this case. Resp. Br. 21–23. The fundamental difference between *Buckman* and this case is that the claim in *Buckman* had no basis in traditional state tort law, because it was asserted against a consulting firm that owed no duty to the plaintiffs. *See* 531 U.S. at 352–53. The Court held that, unlike preemption cases implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety," in *Buckman* "the fraud claims exist solely by virtue of the FDCA disclosure requirements." *Id.* at 348, 352 (quoting *Medtronic*, 518 U.S. at 485).[9] Respondents' claim is entirely different from the plaintiffs' claim in *Buckman* because it arises from the traditional state-

[9] The United States takes the position that "[t]here is . . . no private right of action to enforce the FDCA." U.S. Br. 4 (citing *Buckman*, 531 U.S. at 349 n.4, 352).

law tort duties owed directly to them by petitioners, independent of the FDCA's disclosure requirements.

1. *Non-Compliance with FDA Reporting Requirements Is Not a Unique or Inherently Federal Question That Forecloses Application of the Presumption Against Preemption.*

Petitioners and the United States argue that, rather than being an integral part of traditional state tort law regarding health and safety, a traditional state-law tort claim that implicates fraud on the FDA is "inherently federal in character" and therefore not entitled to the presumption against preemption even when, as here, the provision is part of a state health statute. Pet. Br. 40 (the fact-finder would have to determine whether a defendant "violated *federal law*"); U.S. Br. 14 (presumption does not apply "where the interests at stake are 'uniquely federal' in nature" (quoting *Buckman*, 531 U.S. at 347)). For support, the United States cites *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504–05, 508 (1988), in which this Court held that interpretation of a federal contract was an area of "unique federal concern [that] changes what would otherwise be a conflict that cannot produce pre-emption into one that can." *See* U.S. Br. 14–15.

Petitioners and the United States thus substantially overstate the reach of what is, in fact, a very limited rule. The existence of federal law on a particular subject does not automatically make that subject "inherently federal" in such a way as to eliminate the presumption against preemption. As this Court has stated, "[u]ndoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, how-

ever, that every federal statute ousts all related state law. . . . Instead, we must look for special features warranting pre-emption." *Hillsborough*, 471 U.S. at 719 (declining to find preemption of local ordinance despite existence of a "federal interest" because "the regulation of health and safety matters is primarily, and historically, a matter of local concern").

Whether Warner-Lambert withheld from the FDA information that Rezulin caused liver damage is neither inherently nor uniquely a matter of federal concern. Rather, the issue is relevant both to federal regulation *and* state tort liability because the facts that establish state tort liability may also be characterized as "fraud on the FDA." In these circumstances, no uniquely federal question is posed, and petitioners must overcome the presumption that Congress intended to coexist state and local regulation of health and safety with federal regulation.

2. ***The Presumption Against Preemption Applies in Conflict Preemption Cases.***

The U.S. Chamber of Commerce contends in its *amicus* brief that "no presumption against preemption applies to the judicial determination of whether preemption is necessary because of an 'actual conflict' between state law and valid federal law." C.C. Br. 8. This is simply incorrect. The presumption against preemption has repeatedly been applied by this Court when considering whether actual conflict exists. *See Cipollone*, 505 U.S. at 518 (holding a state tort action not preempted because of "the presumption against pre-emption of state police power regulations" and because "there is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of

state common-law damages actions"); *Hillsborough*, 471 U.S. at 716 ("Appellee must thus present a showing of implicit pre-emption of the whole field, *or of a conflict between a particular local provision and the federal scheme*, that is strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation.") (emphasis added). Furthermore, principles of field and conflict preemption are not "rigidly distinct." *English v. Gen. Electric Co.*, 496 U.S. 72, 79 n.5 (1990). "Indeed, field pre-emption may be understood as a species of conflict pre-emption." *Id.*

Whether or not the term "presumption" is used, this Court has long utilized a practice of examining both the level of state interest and the strength of the perceived conflict when deciding preemption questions. *See American Ins. Ass'n v. Garamendi*, 539 U.S. 396, 420 (2003) ("And since on [Justice Harlan's] view it is legislation within 'areas of . . . traditional competence' that gives a State any claim to prevail, it would be reasonable to consider the strength of the state interest, judged by standards of traditional practice, when deciding how serious a conflict must be shown before declaring the state law preempted." (citation omitted)); *cf. Southern Pac. Co. v. Arizona ex rel. Sullivan*, 325 U.S. 761, 768–69 (1945) (holding, in the Negative Commerce Clause context, that "reconciliation of the conflicting claims of state and national power is to be attained only by some appraisal and accommodation of the competing demands of the state and national interests involved.").

Thus, the exercise of traditional state police powers here—the fundamental difference between the claims in this case and those in *Buckman*—militates

against a finding of preemption, and it is largely a semantic difference whether that analysis is termed a "presumption against preemption," or whether the exercise of state power increases "the strength of the state interest" in balancing state and federal interests to determine whether a conflict exists. Either way, because Michigan has an undeniably strong interest in protecting the health of its citizens, respondents' claims are not preempted under *Buckman*.

II. CONGRESS INTENDED STATE PRODUCT LIABILITY REMEDIES TO COEXIST WITH FDA REGULATION.

The FDCA does not confer upon the FDA the exclusive power to regulate conduct that constitutes fraud and, absent a clear expression of such intent, this Court will not imply it. Moreover, as the FDA concedes that whatever it may be *authorized* to do, it uses the powers vested in it to police fraud to suit its own regulatory purposes and not to protect fraud victims. Consequently, if the Court preempts, it will create an extremely harmful regulatory void that Congress did not intend and leave persons injured by the intentional torts of drug manufacturers without any legal remedy.

A. Congress Has Not Vested the FDA with Exclusive Authority to Regulate Tortious Conduct That Constitutes "Fraud on the FDA."

Congress has rarely expressed an intent to preempt state tort remedies for defective or dangerous drugs, and when it does so, it expresses its intent clearly. Indeed, the House of Representatives has passed several bills that included a provision that, similar to state statutes, would preempt punitive

damages in state products liability cases involving "medical products" or "drugs or devices" where FDA approval was granted. *See, e.g.*, Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2007, H.R. 2580, 110th Cong. (2007); Medical Malpractice Reform Act of 2006, H.R. 4838, 109th Cong. (2006); HEALTH Act of 2005, H.R. 5, 109th Cong. (2005); Common Sense Medical Malpractice Reform Act of 2003, H.R. 321, 108th Cong. (2003); Medical Malpractice Rx Act, H.R. 2103, 107th Cong. (2001).

Like Michigan's statute, however, these bills contained an exception permitting the recovery of punitive damages when the defendant,

> before or after premarket approval, clearance, or licensure of such medical product, knowingly misrepresented to or withheld from the [FDA] information that is required to be submitted under the [FDCA] that is material and is causally related to the harm which the claimant allegedly suffered; or * * * made an illegal payment to an official of the [FDA] for the purpose of either securing or maintaining approval, clearance, or licensure of such medical product.

H.R. 2580 § 7(c)(4); *see also* Mich. Comp. Laws § 600.2946(5)(a)–(b) (using substantially similar language). The bills do not stipulate that such proof of "fraud on the FDA" must be determined by the FDA itself, nor do they seek to preempt the traditional uses of tort law in this area. Rather, they permit a state tort plaintiff to prove "fraud on the FDA" in order to establish eligibility for punitive damages. Such bills therefore reflect the view that pursuing "fraud on the FDA" as part of a state tort lawsuit does not conflict with the FDA's ability to police

fraud. Evidence of fraud is simply relevant to both federal and state concerns. Indeed, if Congress intended to preempt state tort claims because "fraud on the FDA" was an exclusive federal issue, this proposed legislation would not be limited to the recovery of punitive damages.

Moreover, these bills follow an established pattern by Congress, recognized by the Court, not to use Congress's powers of preemption in such a way as to deprive injured parties of all remedies. *See Silkwood*, 464 U.S. at 251 ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."). On the rare occasion Congress has preempted state tort recovery in the area of dangerous drugs, it has expressly provided an alternative mechanism to compensate victims. *See* 42 U.S.C. § 300aa-10–34 (2000) (creating the National Vaccine Injury Compensation Program, preempting tort liability for vaccine manufacturers while also providing a separate method for obtaining compensation for a vaccine-related injury or death).

Congress's actions indicate that it would not erase the long history of state products liability actions and deprive tort victims of traditional remedies without clearly expressing its intent to do so. *See Bates*, 544 U.S. at 449–50 ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." (citing *Silkwood*, 464 U.S. at 251)). Given this history, it is implausible to think that Congress would by implication eliminate all forms of compensation for victims of the most egregious tortfeasors—

those who intentionally withhold information about a drug's toxicity in order to obtain FDA approval.

B. Because the FDA Does Not Consider Abstract Allegations of Fraud and the FDCA Contains No Remedies for Fraud Victims, Preemption Would Create an Extremely Harmful Regulatory Void.

While the FDA possesses various mechanisms to police fraudulent conduct, U.S. Br. 15-16, it apparently does not use them to protect victims of fraud and did not do so here. *See id.* at 21, 24. Moreover, the FDA's position is that there is "no private right of action to enforce the FDCA." *Id.* at 4. Yet respondents' allegations against petitioners, if proven,[10] will establish egregious and fraudulent misconduct that may be tantamount to criminal acts. *See, e.g.*, Resp. Br. 4-5 ("While aware as early as 1993 of Rezulin's potential harm to the liver, Warner-Lambert chose to omit from its FDA submissions information that showed this concern to be valid." (citing David Willman, *Risk Was Known As FDA OKd Fatal Drug*, L.A. Times, Mar. 11, 2001)). What ensued thereafter powerfully demonstrates why Congress did not intend the FDA to have the exclusive power to determine the remedies for persons injured or killed by Rezulin.

Respondents' allegations highlight the FDA's slow response to revelations of Rezulin's toxicity. Despite numerous "reports of serious adverse events [which] started to flow in to the FDA," only months

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[10] As respondents note, the early dismissal of their actions under F.R.C.P. 12(c) left them no opportunity to prove the facts on which they base their claims. Resp. Br. 5 n.1. The factual statement in their brief "reflect[s] what respondents will attempt to prove if the case proceeds." *Id.*

after approval, the agency did not withdraw its approval of the drug. *Id.* at 6. Rezulin was pulled off the market in Britain on December 1, 1997, "because 'the pace of liver injuries and deaths was by that point "unacceptably high."'" *Id.* at 7 (citing JA 34-35). In this country, by contrast, Rezulin was sold until March 2000, when "Warner-Lambert voluntarily withdrew [the drug] from the United States market." Pet. Br. 14. The FDA did not rescind its approval of Rezulin until 2003. 68 Fed. Reg. 1469 (2003).

Between 1997 and 2000, "[r]ather than withdrawing approval, the FDA negotiated a series of labeling changes with Warner-Lambert." Resp. Br. 6. During the three years petitioners marketed Rezulin, they realized approximately $1.8 billion in revenue. JA 28. Yet if petitioners prevail in this Court, they will never have to answer to a single Michigan claim that they wrongfully withheld evidence that Rezulin was too dangerous to be used by diabetics, or that they were engaged in the intentional tort of knowingly selling a toxic drug.

Despite the FDA's "core public health mission," the United States appears to acknowledge that victims of fraud are not a high priority for the FDA. *See* U.S. Br. 24. For example, the agency "does not have a process for considering allegations or making explicit findings of fraud in the abstract. Citizen petitions must seek specific types of administrative action, such as withdrawal of a drug's approval, not merely a finding of fraud." *Id.* (citation omitted). Moreover, "[w]hen FDA suspects fraud, it often reaches a settlement with the applicant in which the applicant pays a fine or takes corrective action (such as changes in labeling) without admitting liability." *Id.* at 24.

The United States thus indicates that the FDA's regulatory and enforcement mechanisms for addressing victims of fraud are not central to the agency's perception of its "core public health mission." *Id.* But given the congruence of the FDA's public health mission and the historic responsibility of the States to protect public health, *see, e.g., Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824); *Oneida-Herkimer*, 127 S.Ct. at 1795, it is inconceivable that Congress intended the FDCA to leave plaintiffs such as respondents without any state remedy simply because proof of petitioners' negligence also establishes a regulatory violation. This is particularly true since the FDA, by its own admission, either ignored or, at best, used the fraud alleged by respondents as a bargaining chip to have Warner-Lambert voluntarily withdraw Rezulin from the market. *See* Resp. Br. 6-7; U.S. Br. 21. Congress would not have intended to preempt state law to leave such a regulatory void in which tort victims could not avail themselves of either federal or state protection.

Members of Congress know that "FDA officials in Washington repeatedly reject[] the recommendations of career field officials urging enforcement actions, even in cases involving death and serious injury." Minority Staff of H. Comm. on Government Reform, *Report on Prescription for Harm: The Decline in FDA Enforcement Action* 6 (June 2006), *available at* http://oversight.house.gov/documents/20060627101434-98349.pdf. Congress is also well aware that state-law tort remedies, not FDA regulation, are the central component of the nation's remedial scheme for persons injured or killed by defective products.

Consequently, and as this Court reasoned in *Pacific Gas & Elec. Co. v. State Energy Res. Conser. & Dev. Comm'n*, 461 U.S. 190, 207–08 (1983), "[i]t is

almost inconceivable that Congress would have left a regulatory vacuum" that the FDA candidly admits exists because it is not required to consider the interests of fraud victims. The "only reasonable inference is that Congress intended the States to continue to make these judgments." *Id.* at 208. The FDA can bargain away its limited interest in pursuing drug company fraud, but it has no authority to bargain away the state-law products liability claims of the victims of that fraud.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER, INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. Member companies are the source of a majority of all new medicines that are discovered and marketed. New medicines accounted for 40 percent of the lifespan increase between 1986 and 2000. *See* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, 21 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003). In the past decade alone, PhRMA's members invested approximately $300 billion to develop new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2007* 42 (2007).

PhRMA's members closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues. PhRMA has a particular interest in cases involving possible state-law interference with the comprehensive public health regulatory regime for prescription drugs administered

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1. Pursuant to Rule 37.1 of the Rules of the Supreme Court of the United States, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

by the Food and Drug Administration ("FDA"). PhRMA supports and endorses this Court's safeguarding of the "inherently federal" relationship between FDA and pharmaceutical manufacturers against state law intrusion based on alleged fraud on the FDA, *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and submitted a brief *amicus curiae* supporting the grant of certiorari in this case. *See* Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Petitioners, Warner-Lambert Co. v. Kent, No. 06-1498 (filed July 20, 2007). PhRMA strongly believes that the Second Circuit's decision was flawed in several respects and asks that this Court reverse the judgment of the court below under the reasoning of its decision in *Buckman*.

INTRODUCTION

In *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that state law claims that authorized recovery against medical device and drug manufacturers where regulatory approval was allegedly procured through "fraud on the FDA" were preempted. The court below, however, upheld a "fraud on the FDA" claim framed as an exception to a Michigan affirmative defense that otherwise insulated FDA-approved drugs from product liability claims. The decision below cannot be squared with this Court's precedent and, if allowed to stand, would evade *Buckman*'s bar on state-law interference in the manufacturer-FDA relationship through only slightly more subtle means. The likely proliferation of state-law fraud on federal regulators litigation and the resulting interference with congressionally granted federal authority that would follow would significantly burden both the health care and judicial systems.

The Second Circuit ruled that because Respondents' causes of action were not grounded *solely* on a fraud-on-the-FDA theory, *Buckman* did not control. The court sought to bolster that contention by characterizing it as the position "the pharmaceutical industry" took in *Buckman*. The court was wrong on both counts. The conflict that drove this Court's preemption decision in *Buckman* arose from the state's assertion of power to review the regularity of FDA approvals under state law, not from the specific role that such review played in state litigation. The industry's position then, as now, is that such review would frustrate the objects and purposes of federal law and cannot be sustained under the Supremacy Clause. Thus, as in *Buckman*, liability here turns on Respondents' ability to prove as a matter of *state law* that Petitioners' FDA approval was obtained through fraud on the FDA. Allowing judges and juries to determine that issue would produce the same interference with FDA's regulatory mandate that led this Court to preempt fraud on the FDA actions in *Buckman*. That the Michigan statute uses the resolution of that question as a means of overcoming an otherwise available product liability defense cannot justify it constitutionally.

In addition, to shore up its faulty interpretation of *Buckman*, the Second Circuit wrongly invoked a "presumption against preemption." The presumption, which is of dubious constitutional heritage generally, has absolutely no place in conflict preemption cases where the rule of decision is provided by Article VI of the Constitution-not, as in express preemption cases, by an Act of Congress. Furthermore, the fact that the Michigan "legislative scheme" addresses product liability does not, as the Second Circuit asserted, alter this conclusion;

indeed, the claims in *Buckman* were allegedly framed within the States' traditional areas of tort action. States cannot obtain the benefit of the presumption by burying interference with an area of traditional federal control in an exception to an affirmative defense. The need to establish fraud on the FDA in order to obtain relief under state law rendered the presumption inapplicable in *Buckman*, and so it does here.

The Second Circuit also ignored the adverse practical consequences of allowing state-law "fraud on the FDA" to be litigated in case after case. Permitting this uniquely federal question to be incorporated into state law would defeat Congress's deliberate decision to grant FDA ample and exclusive authority to establish information filing requirements and police fraud on the agency. The interference that would necessarily flow from state "fraud on the FDA" litigation would disrupt FDA's ability to accomplish the tasks assigned to it by Congress.

State superintendence of "fraud on the FDA," moreover, expressly invites state-law courts to second-guess FDA approval determinations. Michigan permits juries to determine for themselves, under state law, whether (1) there was a fraudulent misrepresentation or omission and (2) if that "fraud" would have led FDA to prevent the product from coming to market or remove an approved product from the market. These highly scientific and technical judgments have been delegated by Congress to an expert agency for a reason. Congress understood that judges and juries facing an injured plaintiff in a single case were not in a position to make complex scientific decisions with consequences that could

have a significant effect on public health for millions of Americans. FDA's expertise and judgment in this area, therefore, has always been entitled to considerable deference-deference that would be denied the agency under the Second Circuit's mistaken rationale.

Upholding the Second Circuit's decision could induce PhRMA's members to adopt a decidedly defensive posture before FDA. Uncertainty as to the scope of potential tort exposure for non-disclosure under state law would create an incentive for drug manufacturers to inundate FDA with information in an effort to ensure that they were not charged with "fraud" under state law for omitting from their approval applications information that a judge or jury later might find "material" to FDA's approval decision. Indeed, manufacturers would be compelled to make such submissions even if FDA expressed no interest in receiving the information since the agency would not be the ultimate arbiter of the fraud question. Manufacturers also would have reason to demand, in order to document these prophylactic submissions, formal and detailed responses from FDA. As explained in *Buckman*, a flood of filings would strain FDA's resources, restrict the agency's ability to effectively balance drug safety and efficacy, and generally undermine the inherently federal FDA-manufacturer relationship.

These constitutional and practical concerns led this Court to conclude in *Buckman* that any state law that required courts to adjudicate "fraud on the FDA" wrongly intruded into an inherently federal relationship

and created an obstacle to the accomplishment of Congress's objectives in the FDA approval process. The Michigan exception requires judges and juries to determine, as a matter of state law, whether FDA approval was procured through fraud. Only if the answer is yes may the case proceed. The Second Circuit's attempt to distinguish this reliance on fraud on the FDA for state remedy administration from the reliance confronted by the Court in *Buckman* utterly fails. For all of these reasons, PhRMA respectfully requests that the Court reverse the decision below.

ARGUMENT

I. *BUCKMAN* REQUIRES PREEMPTION OF THE "FRAUD ON THE FDA" EXCEPTION TO THE MICHIGAN STATUTORY DEFENSE.

A. The Michigan Exception Would Obstruct FDA's Supervision Of Federal Disclosure Requirements In The Same Way As The "Fraud On The FDA" Claim Struck Down In *Buckman*.

The case at bar presented the Second Circuit with a product liability claim against a pharmaceutical manufacturer under Michigan law. *See Desiano v. Warner-Lambert Co.*, 467 F.3d 85, 93 (2d Cir. 2006). Michigan law provides pharmaceutical manufacturers a complete defense against a product liability claim so long as the product at issue is distributed in accordance with FDA rules and regulations. *See* Mich. Comp. Laws § 600.2946(5). The Michigan affirmative defense does not apply, however, if the manufacturer commits material

fraud on the FDA. *See id.* § 600.2946(5)(a) ("This subsection does not apply" if the manufacturer "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted . . . and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted.").

The constitutional viability of this "fraud-on-the-FDA" exception to the Michigan statutory defense depends on the force and meaning of this Court's decision in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the plaintiffs brought state-law causes of action, alleging that a consultant to a medical device manufacturer had made "fraudulent representations" to FDA during the approval process. *See id.* at 343. According to the plaintiffs, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* This Court unanimously ruled that this state-law "fraud-on-the-FDA" claim conflicted with, and "therefore [was] impliedly pre-empted by, federal law." *Id.* at 348; *see also id.* at 353 n.1 (Stevens, J., concurring) (agreeing that "federal law 'pre-empts' this state-law fraud-on-the-FDA claim").

As this Court then explained, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. The federal regime could not properly function "in the shadow of 50 States' tort regimes." *Id.* at 350. Indeed, allowing judges and juries to determine under state law

whether "fraud on the FDA" had occurred would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351. Manufacturers therefore would be prompted to "submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Id.*

In the present case, even though Respondent's ability to recover for product liability under Michigan law also turns on a finding that Petitioners procured FDA approval through fraud, the Second Circuit rejected the applicability of *Buckman* and ruled that the exception to the Michigan statutory defense was not preempted. *See Desiano*, 467 F.3d at 93 (finding a "meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law"); *see also id.* at 94-95 (stating that, in contrast to *Buckman*, none of the claims "derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency"); *id.* at 95 (distinguishing *Buckman* because, in that case, "there were no free standing allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements"). As explained below, the Second Circuit's justifications for distinguishing *Buckman* do not pass muster. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) ("Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*.").

The Second Circuit's central premise was that, unlike in *Buckman*, Respondents' legal claims were not "solely" grounded on a "fraud on the FDA" theory. *See Desiano*, 467 F.3d at 95 (concluding that "unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA" and that "plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime"). Setting aside whether the distinction drawn by the Second Circuit is accurate, it is without a doubt immaterial. This Court's preemption decision in *Buckman* did not turn on whether fraud on the FDA was alone sufficient to trigger liability under state law. Indeed, the parameters of the state law at issue in *Buckman* were not clearly defined, and it is far from certain that a finding of fraud on the FDA would alone have been sufficient to impose liability on the defendant in that case. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998), *rev'd, sub nom. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) ("While it is clear that the plaintiffs' 'fraud on the FDA' claims are based on state rather than federal law, . . . the controlling state law of fraudulent representation in some cases may be different from that in other cases."). Rather, it was the consequences of allowing a plaintiff to prove as a matter of state law that the manufacturer had wrongly obtained FDA approval either by making affirmative misrepresentations or by withholding information from the agency that drove the decision in *Buckman*. *See id.* (explaining that the claim in *Buckman* was "drafted to track the elements of a common law cause of action for fraudulent misrepresentation") (citing Restatement (Second) of Torts § 525 *et seq.*); *see also Buckman*, 531 U.S. at 346-

47 (noting the claims at issue were "state-law causes of action claiming that petitioner and AcroMed made fraudulent representations to the FDA . . . and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment"). On this ground, the case at bar and *Buckman* are indistinguishable.

In fact, none of the reasons articulated for finding preemptive conflict in *Buckman* depended in any way on the fact that the alleged fraud on the FDA was a stand-alone claim. *See id.* at 348 ("The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud."). Instead, the Court preempted the state-law cause of action because "the existence of these federal enactments [was] a critical element in [the plaintiffs'] case," *id.* at 353, and, accordingly, any state-law claim that interfered with the inherently federal relationship between regulated manufacturers and the FDA was foreclosed. *See id.* at 350 (explaining that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA"); *id.* at 351 ("[F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court.").

Here, just as in *Buckman*, liability under state law turns on whether the plaintiff can establish that Petitioners obtained FDA approval through fraud. *See Desiano*, 467 F.3d at 95. Michigan law unquestionably

forces courts to inquire into whether the manufacturer intentionally withheld from or misrepresented required disclosures to the FDA and whether that omission or misrepresentation would have altered FDA's decision to allow the drug to enter or remain on the market. *See* Mich. Comp. Laws § 600.2946(5)(a). This is the precise inquiry that was preempted in *Buckman*. *See Garcia*, 385 F.3d at 965-66 (recognizing that, although the Michigan statute "presents a somewhat different legal regime from the one invalidated in *Buckman*," the "difference . . . is immaterial in light of *Buckman*"); *see also Ledbetter v. Merck & Co.*, Nos. 05-59499 & 05-58543, 2007 WL 1181991 (Tex. Dist. Ct. Harris County Apr. 19, 2007) ("Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply."); *Henderson v. Merck & Co.*, No. 04-CV-05987, 2005 WL 2600220, at *11 (E.D. Pa. Oct. 11, 2005) ("This Court follows the holdings of *Buckman* and *Garcia*, and finds that . . . [Sections] 600.2946(5)(a) and (b) are preempted by the FDCA in most situations.").[2]

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2. Michigan law is clear that, when claiming an exception to an affirmative defense, the burden lies with the plaintiff to show all of the elements of fraud on the agency, and it is properly considered a "claim" that the plaintiff must make. *See Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003); *Feyz v. Mercy Memorial Hosp.*, 719 N.W.2d 1, 10 n.45 (Mich. 2006); *McNeil ex rel. McNeil v. Metinko*, Nos. 194595 & 194596, 1998 WL 2016585, at *1 (Mich. Ct. App. March 13, 1998). The Second Circuit's conclusion that the alleged fraud on the FDA will be raised based on a defendant's invocation of the statutory affirmative defense and "that it is not up to the plaintiff to prove

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To bolster its faulty reading of *Buckman*, the Second Circuit announced that its conclusion was not different from "the position the pharmaceutical industry articulated at oral argument in *Buckman*." *Desiano*, 467 F.3d at 95. In particular, the court relied on a statement made by Buckman's counsel: "The plaintiffs don't claim that these devices were in any way defective. . . . Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices." *Id.* at 95-96 (quoting Oral Argument Transcript, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 2000 WL 1801621 (2000) (No. 98-1768) (hereafter "*Buckman* Transcript")); *see also id.* at 96 n.8 (concluding that "a second lawyer for the industry indicated that traditional tort remedies were *not* implicated by *Buckman*" because "[w]hen asked about what remedies an injured plaintiff would have under his theory of the case, the attorney responded: 'The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available[.]'") (quoting *Buckman* Transcript at *21).

These statements should not have been attributed to the "pharmaceutical industry"; they were instead advanced by the Petitioner in *Buckman*-a consulting

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fraud as an element of his or her claim," *see Desiano v. Warner-Lambert Co.* 467 F.3d 85, 96 (2d Cir. 2006), thus coyly, but unsuccessfully, sidesteps the dispositive question—*i.e.*, which party bears the ultimate burden of proof. The Second Circuit did not—and could not—dispute that the ultimate fraud burden resides with the plaintiff under Michigan law.

company for medical device manufacturers-and by the United States government. *See id.* at 95; *Buckman* Transcript at *3-4, 21. PhRMA, which does represent "the pharmaceutical industry," in fact filed an *amicus curiae* brief in *Buckman*. *See* Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Petitioner, Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2000) (No. 98-1768). The positions taken in that brief are in complete accord with the position taken here. *See id.* at 6 (explaining that federal law "require[d] preemption of state-law standards that permit[ted] the states to scrutinize the FDA approval process and second-guess the validity of FDA approval determinations" and that "[t]hese standards, whether imposed through common-law causes of action or statutory schemes, would impermissibly disrupt the intended uniformity and certainty of the federal approval regime, and could lead to reduced availability of important medical products"); *id.* at 14 (taking the position that "[t]he integrity of the FDA approval regime requires preemption of state-law standards-including respondents' 'fraud on the FDA' claims-that permit ad hoc (or systematic) challenges to the validity of FDA approval decisions").

Moreover, the Second Circuit completely mischaracterizes the arguments advanced by Buckman's counsel at oral argument. Counsel stated that "the plaintiffs' sole claim" was fraud on the FDA and that the plaintiffs did not claim that the devices were defective. *Buckman* Transcript at *3-4. Counsel did not argue that these distinctions were in any way material to the question before the Court, and certainly did not suggest that the case should come out any differently if

fraud on the FDA were only one part of a claim or a "necessary proof" element of a case. That issue was not before the Court, and the *Buckman* Petitioner would have had no reason to draw such a distinction. Indeed, portions of the argument before the Court omitted from the Second Circuit's discussion of this issue make clear that Buckman's position would have been the same even if the claim at issue was not based "solely" on fraud on the FDA:

> So this lawsuit is, in other words, a direct attack under State law on the decision of the Federal Food & Drug Administration[.] . . . [I]t means that a jury applying State law would have to decide such issues as, what sorts of disclosures have to be made to the Food & Drug Administration[?] What did the FDA know[?] Was the FDA deceived in any way in granting regulatory clearance?

Buckman Transcript at *4; *see also id.* at *9 ("[T]he point that I was simply making is the sorts of inquiries that a State judge or jury would have to make if this State law claim were allowed to proceed are inquiries that would delve heavily into the intricacies of the Federal regulatory process[.]").

Moreover, the United States, arguing in support of the Petitioner in *Buckman*, articulated exactly the point being made by the Petitioner and by PhRMA here: "[I]nsofar as they would be asserting an essential element of the claim . . . that the FDA was defrauded, that is an area of exclusive Federal concern, and the State common law cause of action would be preempted."

Id. at *21. Put simply, the record does not support any contention that the pharmaceutical industry conceded in *Buckman* the validity of a law such as the one at issue here. The Second Circuit's contrary makeweight is unsustainable.

B. The Second Circuit Erred In Applying A Presumption Against Preemption In This Case.

This Court, at times, has endorsed a "presumption against preemption" under which the review of a federal statute "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, (1947); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523-24 (1992) ("[W]e must fairly but-in light of the strong presumption against pre-emption-narrowly construe the precise language of § 5(b) and we must look to each of petitioner's common-law claims to determine whether it is in fact pre-empted."). The court below found that a presumption against preemption applied in this case. *See Desiano*, 467 F.3d at 93 ("[T]he presumption against federal preempt-ion of state law obtains in the case before us."). The Second Circuit's invocation of a "presumption" in the case at a bar was deeply flawed for at least two reasons.

First, a presumption against preemption has no legitimate role in conflict preemption cases. When Congress exercises its Article I power to occupy an area of commerce, or to foreclose state activity in a traditional area of state concern, without regard to a conflict of commands or purposes, principles of federalism might

properly counsel requiring a clear legislative articulation of the bounds of that foreclosure. *See, e.g., De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813-14 (1997) (invoking a "presumption against preemption" to determine "the scope of the state law that Congress understood would survive" (citations and internal quotations omitted)); *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) (explaining that the "principle to be derived from" past Supreme Court "decisions is that federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons-either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained."). That invocation of the "presumption" essentially supplies guidance in cases where it is unclear whether Congress intended to trump state law by positive enactment. *See, e.g., Cipollone*, 505 U.S. at 518 ("This presumption reinforces the appropriateness of a narrow reading of § 5.").

Where, however, the exercise of state authority would impose duties inconsistent with federal mandates or obstruct the objects and purposes of federal law, preemption arises directly from Article VI of the Constitution. The relevant Congressional intent relates to how Congress expects the federal regime to operate-an issue to which the presumption has no relevance. *See Chicago & Nw. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (explaining that conflict preemption analysis entails "essentially a two-step process of first ascertaining the construction of the two statutes and then determining the constitutional question whether they are in conflict") (citations and

quotations omitted); *Fla. Lime*, 373 U.S. at 142-43 ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."). Thus, for example, this Court determined the objects of National Highway Traffic Safety Administration's passive restraint regulation without regard to any presumption. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874-75 (2000) ("In a word, ordinary pre-emption principles, grounded in longstanding precedent apply." (internal citation omitted)). Having given appropriate deference to the operation of the federal regimes, the Court properly secured them from state interference. *See id.* at 875-86.

As this Court explained, if "the state law regulates conduct that is actually protected by federal law . . . pre-emption follows not as a matter of protecting primary jurisdiction, but as a matter of substantive right." *Brown v. Hotel & Rest. Employees and Bartenders Int'l Union Local 54*, 468 U.S. 491, 503 (1984). In this context, unlike with respect to Congressional preemption by exclusion, any substantive federalism concerns were resolved when the Framers chose to make federal law supreme. *See id.* at 503 (explaining that when "the issue is one of an asserted substantive conflict with a federal enactment, then '[t]he relative importance to the State of its own law is not material . . . for the Framers of our Constitution provided that the federal law must prevail'") (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) (explaining that under the Supremacy Clause "[t]he relative importance to the State of its own law is not

definition more difficult in implied preemption cases, where Congress has not codified its intent expressly. But it is most difficult in "obstacle" or "frustration of purpose" cases, which often arise under broad congressional mandates ordering administrative agencies to set minimum safety standards or labeling requirements.[23] In this context, neither the statutes nor their legislative histories provide much – if any – useful evidence regarding congressional intent on preemption. In such cases, courts must undertake the difficult task of attempting to discern the "full purposes and objectives" embodied in a statute or even a *regulatory framework* that does not speak directly to the issue of preemption – a controversial inquiry in which judges have scant guidance. And even if it were possible to ascertain the full purposes of a law or regulation, this Court has recognized that no law is intended to pursue its purposes at all costs.[24] Thus,

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Malone, 435 U.S. 497 at 504)); *see also English*, 496 U.S. at 78-79 ("Preemption fundamentally is a question of congressional intent. . . ."); *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996) (stating that the question of preemption "is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State?").

[23] *See, e.g.*, *Bates*, 544 U.S. 431; *Sprietsma*, 537 U.S. 51; *Geier*, 529 U.S. 861.

[24] *See, e.g.*, *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646-47 (1990) (quoting *Rodriguez*, 480 U.S. at 525-26 ("[N]o legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice – *and it frustrates rather than effectuates*

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even in a case where a court is able to ascertain the federal purposes underlying a particular statute or regulation, notwithstanding the absence of an express congressional command, the question whether those purposes would be so deeply undermined by state tort law as to require the obliteration of victims' rights to seek compensation for their injuries requires a delicate inquiry that risks undermining the core federalism principles on which this country was based.

The broad range of potential intentions regarding a law's potential costs – including the obliteration of state law through preemption – only counsels further in favor of the presumption.[25] Courts have little basis on which to discern whether statutes or regulations that do not speak to preemption were intended to supplement state law, to preempt state law, or neither, and they lack the expertise to determine what would be best as a matter of policy. Apparently recognizing this problem, this Court's most recent decisions properly rejected arguments that statutes and regulations preempt state tort law absent clear evidence of a direct conflict with federal purposes. *See Bates*, 544 U.S. at 449-51; *Sprietsma*, 537 U.S. at 64, 65.

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legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law.") (emphasis added)).

[25] *See, e.g.*, Frank H. Easterbrook, *Statutes' Domains*, 50 U. CHI. L. REV. 533, 548 (1983) ("[J]udicial predictions of how the legislature would have decided issues it did not in fact decide are bound to be little more than wild guesses. . . .").

The vital importance of the presumption against preemption is underscored by another recent development: Federal agencies have embarked on an unprecedented attempt to influence the courts by voicing positions on preemption either in litigation or in preambles to regulations.[26] In many cases – particularly where the agency has previously argued that state law is *not* inconsistent with federal purposes (and thus is not preempted) – these positions are demonstrably unstable and politicized, therefore failing to represent the faithful, considered interpretation of congressional intent and regulatory needs.[27] For example, in *Bates*, this Court rejected preemption arguments by the Solicitor General that flatly contradicted the EPA's position in the California Supreme

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[26] *See generally* William Funk, et al., *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety*, White Paper No. 704, at 6-9 (2007), *available at* http://www.progressivereform.org/articles/Truth_Torts_704.pdf.

[27] *See, e.g.*, Vladeck, 33 PEPP. L. REV. at 123 ("There is no dispute that the FDA's new position on the scope of the MDA preemption provision represents a 180-degree shift of position for the agency."). It is also unclear that administrative agencies have the authority to speak directly to preemption unless Congress has granted them that authority, and further unclear that Congress can grant them that authority without violating the separation of powers under the Constitution. *See, e.g.*, Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 331 (2000) (arguing that congressional rather than administrative decision making on preemption is "an important requirement in light of the various safeguards against cavalier disregard of state interests created by the system of state representation in Congress").

Court just four years earlier. *See* 544 U.S. at 437 & n.7; *id.* at 448-49 (rejecting Solicitor General's arguments as "particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."). The ubiquity of these new regulatory preemption efforts – which have occurred across numerous agencies and subject matters, without regard to whether Congress has altered the underlying statutes[28] – evidences a broad program of preemption by the executive branch that has nothing to do with congressional intent – and often directly undermines it. The presumption against preemption helps to ensure that courts will not rely on these or other improper arguments for the expansion of federal authority by instructing them to find preemption only when it is the "clear and manifest" intent of Congress.

For all of these reasons, the doctrine of "obstacle" or "frustration of purpose" preemption is fraught with potential for improper expansions of federal power and curtailment of the states' historic power to protect their citizens. The presumption against preemption serves as a crucial counterweight.

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[28] *See generally* Funk et al., *The Truth About Torts*, at 6-9.

B. The Chamber of Commerce's Policy Arguments Against the Presumption Are Overreaching and Unpersuasive.

1. The Chamber's claim that the presumption is not supported by federalism concerns, *see* Chamber Br. 6, 15-16, contradicts this country's core political values and the consistent teachings of this Court. For the reasons discussed above, the presumption against preemption is grounded in sound federalism policy dating back hundreds of years. In contending the opposite, the Chamber relies on a handful of law review articles and selective quotes from opinions that actually *support* the presumption. For example, the Chamber quotes *DeCanas v. Bica*, 424 U.S. 351 (1976), for the proposition that "even state regulation designed to protect vital state interests must give way to paramount federal legislation." Chamber Br. 16 (citing 424 U.S. at 357). But the very next sentences in that case reaffirm the presumption, stating, "[b]ut we will not presume that Congress . . . intended to oust state authority. . . . Only a demonstration that complete ouster of state power including . . . laws not in conflict with federal laws was 'the clear and manifest purpose of Congress' would justify that conclusion." 424 U.S. at 357. Indeed, *DeCanas* endorses perhaps the strongest form of the presumption, stating that "the proper approach is to reconcile 'the operation of both statutory schemes with one

another rather than holding (the state scheme) completely ousted.'" *Id.* at 358 (citation omitted).[29]

The Chamber engages in similarly selective reading of the commentators. For example, it relies heavily on Professor Caleb Nelson's argument against the presumption. *See* Chamber Br. 17, 19 (citing Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 293, 238-44, 254-60, 300, 302 (2000)). But it does not mention that Professor Nelson's argument addresses *express* preemption. *Id.* at 293-94. Even more telling, the Chamber fails to note that Professor Nelson rejects the doctrine of "obstacle" preemption outright, *id.* at 265-90 – a position that would compel resounding defeat for the petitioner here.

2. The Chamber also argues that the presumption is unnecessary in implied conflict cases because, in such cases, courts need only determine the "substance" of a federal statute – which the Chamber believes has nothing to do with preemption – and then determine whether the substance of federal law

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[29] The Chamber also relies on a dissenting opinion that endorses the presumption, disputing only whether it should apply to questions regarding the *scope* of express preemption provisions. *Compare* Chamber Br. 14 (citing *Cipollone*, 505 U.S. at 544 (Scalia, J.) [*sic*]) *with Cipollone*, 505 U.S. at 545 (Scalia, J., dissenting) (endorsing the "traditional principles" of preemption, which include the requirement that congressional intent to preempt be "clear and manifest," then critiquing the majority's use of the presumption not to determine whether an express preemption is preemptive, but rather to determine the *scope* of the provision).

conflicts with state law. In the Chamber's view, this inquiry is different from those regarding field or express preemption questions because it does not require discerning congressional intent. The Chamber is deeply mistaken.

In reality, discerning congressional intent is as important in implied conflict cases as it is in all other preemption cases, for congressional intent is the "touchstone" of preemption.[30] The major difference between express and implied preemption cases is that intent is much more difficult to discern in the latter – providing only a stronger justification for the presumption.[31]

The Chamber is also mistaken in believing that the "substance" of federal laws can be disentangled easily from their preemptive effect. There is a vast difference between a federal regulatory regime that sets a minimum safety standard and is silently intended to be supplemented by tort litigation and one that sets both a "floor" and a "ceiling" with regard to safety and is silently intended to displace tort law, leaving all injured victims with no compensation. This difference is surely one of "substance," yet it also goes to the core of the preemption analysis. Put another way, a federal law may be intended to incorporate state law; to be supplemented by state law without incorporating it; to operate without

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[30] *Cipollone*, 505 U.S. at 516.

[31] *See supra* § II.A.

preemption even when superceded by state law; to preempt only conflicting state law; or to preempt all state law in the area. To call these aspects of a law something other than "substance" is to engage in little more than wordplay.[32] In effect, the Chamber's proposed preemption framework improperly assumes away the question, for it omits the possibility that Congress might have intended to incorporate, accommodate, or leave state law undisturbed.[33]

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[32] Countless federal provisions could be labeled either "substantive" or "preemptive." Professor Nelson explains, for example, that the Supreme Court has labeled "substantive" § 2 of the Federal Arbitration Act, 9 U.S.C. § 2 (2008), which states that a written arbitration agreement in a "contract evidencing a transaction involving commerce" shall be "valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract." *See Southland Corp. v. Keating*, 465 U.S. 1, 15 n.9 (1984). But one could draft a nearly identical express preemption provision, stating that "no state or local government shall adopt or enforce any law or policy that makes a written arbitration agreement in a contract evidencing a transaction involving commerce invalid, revocable, or unenforceable, save upon such grounds as exist at law or in equity for the revocation of any contract." Nelson, 86 VA. L. REV. at 299.

[33] Indeed, the Chamber attempts to support this argument primarily by citing a case that did not even decide a preemption question. *See* Chamber Br. 18, 19 (citing *Smiley*, 517 U.S. at 744). *Smiley* explained that the question whether the statute at issue was preemptive had been decided long ago, in *Marquette National Bank of Minneapolis v. First of Omaha Service Corp.*, 439 U.S. 299 (1978). Therefore, the Court explained, *Smiley* itself concerned only the substantive meaning of the statute – in particular, the definition of the term "interest." *See* 517 U.S. at 744. In light of the Comptroller of the Currency's regulation on

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3. Finally, it is noteworthy that the Chamber's arguments apply not just to implied conflict preemption, but to all preemption cases. Its sweeping dismissal of "the free-form concept 'federalism concerns,'" Chamber Br. 6; *see also id.* 15-16, cannot be limited to implied conflict cases. If federalism is insufficient justification for applying the presumption in implied conflict cases, where Congress has not even made its intentions clear, then states' rights should be accorded even less respect in cases where Congress has exerted federal power more clearly. Similarly, the Chamber's argument that courts should abandon the presumption and instead simply read the substance of federal law, and then call conflicts as they see them, applies *more* readily to express and field preemption than to implied conflict preemption. (Regarding express preemption, the logical outgrowth of the Chamber's argument is that there is no need for a presumption because the intent of Congress is explicit, and therefore courts should read its words without biasing the inquiry.[34] Regarding field preemption, the argument would be that there is no need for a presumption because courts need only discern the content of federal

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the matter, the Court answered this question with an ordinary *Chevron* analysis. *Id.* at 744-45.

[34] This type of strict-construction argument of course carries the corollary that there should be *no* "obstacle" preemption, which by definition entails finding preemption from sources other than the text of statutes or regulations. *See, e.g.*, Nelson, 86 VA. L. REV. at 265-90.

law to determine the "field" it covers, and then hold that any conflicting state law is void.)

That the Chamber's argument for jettisoning the presumption against preemption applies to all preemption cases may be unsurprising given the malleability of preemption categories. *See supra* n.5. But it is noteworthy, for it reveals the astonishing breadth and novelty of the Chamber's position. Although the Chamber claims to challenge the presumption merely in implied conflict cases, its arguments inevitably amount to an attack on the presumption in *all* preemption cases – an argument wildy divergent from this nation's long-established law and values. In essence, the Chamber advocates federal judicial overreaching that would dramatically frustrate democratic governance and uproot the states' historic power to protect the health and safety of their citizens. These arguments should be rejected.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*

The Washington Legal Foundation ("WLF") is a non-profit, public-interest law and policy center based in Washington, D.C., with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free enterprise principles, individual rights, a limited and accountable government, and the proper use of our state and federal judicial systems. To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke*, 529 U.S. 89 (2000).

WLF is particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that frustrates the objectives or operation of specific federal regulatory regimes, such as the Federal Food, Drug, and Cosmetic Act (FDCA) at issue here.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing due solely to its interest in the important preemption issues raised by this case.

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[1] WLF hereby affirms that no counsel for either party authored any part of this brief, and that no person or entity other than *amicus curiae* and its counsel provided financial support for the preparation and submission of this brief. By blanket letters of consent, all parties have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court unanimously held that plaintiffs' claims that a medical device manufacturer secured FDA approval for a § 510(k) medical device through fraud on the FDA were impliedly preempted because such claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgments and objectives." *Id.* at 350. In so ruling, this Court rejected plaintiffs' assertion that it should apply a presumption against preemption to such claims, explaining that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied'" and noting that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347.

Just six years after its clear ruling in *Buckman*, this Court is again faced with the issue of whether fraud-on-the-FDA claims are preempted. In its ruling below, the Second Circuit rejected the core holding of *Buckman* and held that fraud-on-the-FDA claims asserted by plaintiffs to meet the exception to Michigan's product liability statute are *not* preempted. The Second Circuit reached this contrary result based in large part on its holding that it should apply the very same presumption against preemption this Court rejected. *See* Pet. App. 18a-19a.

WLF files this *amicus* brief because the Second Circuit's confusion over the proper scope of a presumption against preemption highlights the need for further guidance on the

issue by this Court.[2] While the claims here should be held preempted even if a presumption applied, the arguments contrary to a presumption against preemption here are in fact far stronger than they were in *Buckman*, because the degree of federal involvement in the approval of prescription drugs dwarfs that at issue in the approval of § 510(k) medical devices. More fundamentally, however, a presumption against preemption is completely inapplicable here because plaintiffs' fraud-on-the-FDA claims (1) intrude upon regulatory determinations within the primary jurisdiction of FDA and (2) conflict directly with federal law. WLF respectfully requests that the Court clarify that no anti-preemption presumption can be applied in such circumstances.

ARGUMENT

I. THE FEDERAL PRESENCE IN THE REGULATION AND APPROVAL OF PRESCRIPTION DRUGS IS FAR MORE SIGNIFICANT THAN THE FEDERAL PRESENCE THAT LED THIS COURT TO REJECT THE PRESUMPTION AGAINST PREEMPTION IN *BUCKMAN*

In applying a presumption against preemption, the Second Circuit failed to recognize the longstanding, extensive role that the federal government plays in the approval of the safety and efficacy of prescription drugs. "[A]n 'assumption' of nonpre-emption is not triggered when the State regulates in

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[2] As the Court has recently noted, the proper application of a "presumption against preemption" is an issue "on which not all Members of this Court agree." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004).

an area where there has been a history of significant federal presence." *United States v. Locke*, 529 U.S. 89, 108 (2000).

In rejecting any presumption against preemption in *Buckman*, this Court focused on the federal interest in maintaining control over the FDA regulatory process by which medical device applicants secure approval for Section 510(k) medical devices. As the Court explained, "the § 510(k) process sets forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device." *Buckman*, 531 U.S. at 348. Accordingly, the Court concluded that policing fraud against the FDA in the Section 510(k) process "is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347.[3]

For prescription drug manufacturers pursuing a new drug application (NDA), far more even than for manufacturers of Section 510(k) devices, the manufacturers' "dealings with the FDA [a]re prompted by the [FDCA], and the very subject of [the applicants'] statements [are] dictated by that statute's provisions." *Id.* at 347-48. This Court recognized in *Buckman* that the Section 510(k) process "lacks the . . . rigor" of FDA's premarket approval (PMA) review of Class III medical devices, *id.* at 348, a process modeled after and substantially

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[3] Like the fraud-on-the-FDA claims at issue in *Buckman*, under the Michigan statutes, plaintiffs seeking to bring claims against a prescription drug manufacturer must establish that the manufacturer "[i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the [FDCA]" and "the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a), reprinted at Pet. App. 42a.

identical to FDA's NDA process for prescription drugs.[4] As the Court previously had noted in *Medtronic, Inc. v. Lohr*:

> The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. . . . As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits negative response from the FDA, and gets processed very quickly.

518 U.S. 470, 478-79 (1996) (citations omitted).

Nevertheless, the *Buckman* Court rejected a presumption against preemption because "to achieve its limited purpose, the § 510(k) process imposes upon applicants a variety of requirements that are designed to enable the FDA to make its statutorily required judgment as to whether the device qualifies under this exception." 531 U.S. at 348-49.

The requirements imposed by FDA on manufacturers of prescription drugs and the corresponding scope of the federal presence mandating the inapplicability of a presumption against preemption here are far more detailed and substantial. Like PMA-approved Class III medical devices, prescription drugs are subject to perhaps the most extensive federal regulatory scheme governing any consumer product. As the

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[4] *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 794 (2002) ("The substantial similarity between the premarket approval process [for medical devices] and new drug application processes compels the conclusion that the latter also establishes a federal requirement with respect to labeling that can have preemptive effect.").

United States Congress recognized a decade ago, the NDA process is rigorous; new drug applications "typically run to hundreds of thousands of pages," and the process of securing NDA approval for a prescription drug "takes an average of 15 years and costs in the range of $500 million." Food and Drug Administration Modernization Act of 1997, S. Rep. 105-43, *available at* 1997 WL 394244, at *6. These costs have only increased since. *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Economics 151-85 (2003) (calculating that total R&D costs per new drug brought to market in the United States have now reached $802 million).

A drug manufacturer seeking approval to market a prescription drug is subject to specific FDA regulatory determinations at every stage of the pre-approval development, approval, labeling, marketing, and post-marketing approval process. To obtain FDA approval of a prescription drug, a pharmaceutical company must submit voluminous scientific evidence to the agency in accordance with the statutory requirements set forth in Section 355 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*.

Pursuant to a broad grant of regulatory authority under the Act, FDA has enacted detailed regulatory reporting requirements for New Drug Applications addressing, *inter alia*, the format and organization of the application, pharmacologic and toxicologic studies, clinical investigation data, case reports forms, patent information, and marketing-exclusivity issues. *See* 21 C.F.R. § 314.50. Once a drug has received FDA approval, FDA continues to subject drug manufacturers to extensive regulatory requirements mandating frequent submissions of adverse drug experience reports, *see* 21 C.F.R. § 314.80, and regular submissions of new studies and other information relevant to the continued approval of the

drug, *see* 21 C.F.R. § 314.81. FDA may also require Phase IV post-marketing studies to gather additional information regarding the drug's safety, efficacy, or optimal use. *See* 21 U.S.C. § 356b. FDA retains continuing regulatory control over the content and format of drug labels. *See* 21 C.F.R. § 201.57; *see also* 21 C.F.R. Part 201. FDA's postmarketing authority has been enhanced further through the recent enactment of the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, §§ 901-21, 121 Stat. 823 (2007).

FDA also imposes strict regulatory requirements on drug manufacturers in their direct communications with physicians. *See* 21 C.F.R. § 200.5 ("mailing of important information about drugs"); § 201.57 and Part 201 (labeling); Part 202 ("Prescription Drug Advertising"); Part 203 ("Prescription Drug Marketing"). In seeking to market a drug to physicians, pharmaceutical companies also are required to "submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product." 21 C.F.R. § 314.81(b)(3). If the company fails to submit such information to the FDA, the agency "may withdraw approval of the application and, thus, prohibit continued marketing of the drug product." *Id.* § 314.81(d).

FDA comprehensively regulates the content and format of prescription drug advertising, including requiring that the advertisement "present a 'true statement' of information in brief summary relating to side effects, contraindications, and effectiveness," *id.* § 202.1(e)(5), and prohibiting advertisements that – as defined in detail in the regulations – are or may be "false, lacking in fair balance, or otherwise misleading," *id.* § 202.1(e)(6) & (7). The FDA vigorously

monitors drug company communications with the medical community and takes regulatory action where it deems such action is appropriate.[5] *See also Penn. Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239 (3d Cir. 2007) (holding consumer fraud claims against prescription drug manufacturers impliedly preempted); *id.* at 250 (Supreme Court opinions in "*Medtronic* and *Geier* add to the preemption analysis by suggesting that state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority").

The federal presence here is also stronger than that in *Buckman* because the federal government's role in the approval of prescription drugs substantially predates its role in the regulation of medical devices. In discussing the competing state and federal interests in the safety of Section 510(k) medical devices in *Lohr*, this Court noted that "[d]espite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasing role in the protection of the health of our people." *Lohr*, 518 U.S. at 475. The Court explained, however, that the FDA had not been authorized to regulate the approval of medical devices until the enactment of the Medical Device Amendments of 1976, some twenty years before. *Id.* at 475-76. In sharp contrast, FDA began regulating the approval of prescription drugs with the enactment of the Food and Drug Act of 1906. The federal government has thus played a central role in ensuring the safety of prescription drugs for over one hundred years.

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[5] For example, in 2005, FDA issued 102 drug warning letters to drug manufacturers in connection with promotional activity. *See* Trends in FDA Drug Enforcement 2006: An Expert Analysis of the Latest Warning Letters (FDAnews Management Report 2006).

The federal interest in maintaining control over the relationship between FDA and prescription drug manufacturers in the NDA process is substantial and would be significantly impeded if courts could misuse a presumption against preemption to allow fraud-on-the-FDA claims under the Michigan statute. The substantial nature of the federal interest in the disclosures to FDA as part of the regulation of prescription drugs was clearly explained in January 2006, when the FDA promulgated a Final Rule on labeling for prescription drugs. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

In the preamble to this Final Rule, FDA warned that in recent years, state law "product liability lawsuits have directly threatened the [FDA's] ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the [FDCA]." *Id.* at 3934. FDA explained that "[s]tate law actions can rely on and propagate interpretations of the [FDCA] and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate." *Id.* FDA thus stressed that "[i]f State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation would be disrupted." *Id.* at 3969.

It cannot be disputed that "there has been a history of significant federal presence" in the regulation and approval of prescription drugs, a federal presence far more significant than that which led this Court to reject a presumption against

preemption in *Buckman*. Whereas the *Buckman* Court confronted the adverse consequences of fraud-on-the-FDA claims only in the context of a limited Section 510(k) review, in this case, the Court is faced with claims that would interfere with scores if not hundreds of different FDA submission requirements that are routinely imposed on drug manufacturers during each stage of the multi-year NDA process and during FDA's subsequent oversight of approved drugs. The Second Circuit's reliance on a presumption against preemption below was in error, and this Court should so hold.

II. THERE IS NO PRESUMPTION AGAINST PREEMPTION WHERE A STATE LAW CLAIM INTRUDES UPON A FEDERAL AGENCY'S PRIMARY JURISDICTION

The Second Circuit's reliance on a presumption against preemption is also in error because it fails to account for the fact that the questions that must be resolved under the Michigan statute fraud on the FDA exception would require a court to intrude upon the primary jurisdiction of FDA. A presumption against preemption is not appropriate where it would undercut the discretion and expertise entrusted by Congress to the federal agencies, which this Court has consistently protected. *See, e.g.*, *Buckman*, 531 U.S. at 347-53 (no presumption against preemption given FDA's primary responsibility to police fraud against the Agency); *Brown v. Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 502 (1984) (NLRB's primary jurisdiction protected by special "presumption [in favor] of federal preemption [that] applies even when the state law regulates

conduct only arguably protected by federal law.");[6] *Far East Conference v. United States*, 342 U.S. 570, 574-75 (1952) (action should be dismissed to afford agency with primary jurisdiction opportunity to review in first instance).

The Court explained the need to not lightly intrude on a federal agency's primary jurisdiction over fifty years ago:

> [I]n cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. This is so even though the facts after they have been appraised by specialized competence serve as a premise for legal consequences to be judicially defined. Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure.

Far East Conference, 342 U.S. at 574-75.

Each of the two showings necessary to invoke the fraud on the FDA exception in the Michigan products liability statute requires a factfinder under state law to intrude upon FDA's primary jurisdiction:

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[6] While *Brown* addressed a special preemption doctrine applicable to matters within the primary jurisdiction of NLRB, the principles behind the Court's rejection there of any presumption against preemption are equally applicable here.

First, the factfinder is required to determine that the drug manufacturer has intentionally withheld from or misrepresented information to the FDA concerning its drug that is required to be submitted under the FDCA. *See* MICH. COMP. LAWS § 600.2946(5), reprinted at Pet. App. 42a. But as this Court recognized in *Buckman*, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives" that "can be skewed by allowing fraud-on-the-FDA claims under state tort law." 531 U.S. at 348; *see also id.* at 349 ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration."). Thus, for example, this Court has held that courts may not review FDA determinations whether to take enforcement action with regard to prescription drugs. *See Heckler v. Chaney*, 470 U.S. 821 (1985). The Court explained that "an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise" and that "[t]he agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Id.* at 831-32; *see also Schering Corp. v. Heckler*, 779 F.2d 683, 685-86 (D.C. Cir. 1985) (decision by FDA whether to exercise its enforcement authority "involve a complex balancing of an agency's priorities, informed by judgments 'peculiarly within its expertise,' and they are therefore ill-suited for judicial review") (internal citation omitted).

The unavoidable intrusion upon FDA's primary jurisdiction required for purposes of determining whether FDA has been defrauded is particularly significant because of the complexity of FDA regulations regarding the information that should be provided to FDA by drug companies and FDA's

discretion in many instances in determining whether or not certain types of information should be submitted. Thus, "it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency's approval." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005); *cf. Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) ("agency decisions are frequently of a discretionary nature or frequently require expertise," resulting in "administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations").

Second, under Michigan's fraud on the FDA exception, the factfinder must determine that the drug would not have been approved or would have had its approval withdrawn if the information had been accurately submitted. *See* MICH. COMP. LAWS § 600.2946(5), reprinted at Pet. App. 42a. This Court has recognized FDA's primary jurisdiction over the NDA approval of prescription drugs. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 654 (1973). "The determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations. Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the administrative agency, while the court stays its hand." *Id.*

Under the Michigan statute, plaintiffs must establish that "the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." MICH. COMP. LAWS § 600.2946(5), reprinted at Pet. App. 42a. Thus, "an essential element of proof . . . would be a showing that if the FDA had passed upon [a prescription drug] according to statutory and constitutional

standards, it would have been approved or exempted." *Tutoki v. Celebrezze*, 375 F.2d 105, 107 (7th Cir. 1967). As the United States Court of Appeals for the Seventh Circuit has explained, "[t]his determination is a matter within the primary jurisdiction of the FDA. *Id.* "The possible conflict of a judicial determination of this question with a[n] . . . FDA determination on [the drug] strengthens our view that the doctrine of primary jurisdiction should be applied." *Id.*; *cf. Rutherford v. United States*, 806 F.2d 1455, 1461 (10th Cir. 1986) ("[T]he intent behind the [FDCA] was to give the agency the primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise. *See also CIBA Corp. v. Weinberger*, 412 U.S. 640, 643-44 (1973).").

By failing to recognize FDA's primary jurisdiction over both steps in the Michigan statute's fraud on the FDA exception, the Second Circuit erroneously hinged its opinion on a presumption against preemption. No such presumption applies here.

III. THERE IS NO PRESUMPTION AGAINST IMPLIED CONFLICT PREEMPTION

Thirdly, the Second Circuit erred in relying on a presumption against preemption because such presumption, if ever appropriate, is not appropriate in cases giving rise to implied conflict preemption. Rather, the sole question for the courts in determining whether implied conflict preemption applies is the existence of a conflict between federal and state law.

The Court repeatedly has made clear that "'[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of

our Constitution provided that the federal law must prevail.'" *Fidelity Fed. Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (principle that "state law is nullified to the extent that it actually conflicts with federal law" is "not inapplicable here simply because real property law is a matter of special concern to the States"); *Brown*, 468 U.S. at 502-03 (same with respect to local interest in crime control). Indeed, even where the State has a "compelling interest" in preservation of its law, "under the Supremacy Clause, for which our preemption doctrine is derived, any state law, . . . clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (internal quotations and citations omitted); *DeCanas v. Bica*, 424 U.S. 351, 357 (1976) ("[E]ven state regulation designed to protect vital state interests must give way to paramount federal legislation."); *Free v. Bland*, 369 U.S. 663, 666 (1962)(same) (citing *Gibbons v. Ogden*, 22 U.S. 1 (1824)).[7]

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[7] Counsel has found no case in which the Court has relied on a presumption against preemption in the face of an actual conflict between state and federal law. In *California v. ARC Am. Corp.*, 490 U.S. 93, 101-06 (1989), the Court suggested a presumption against preemption, but any such presumption played no ascertainable part in the Court's holding. *See id.* (mentioning presumption as something to "overcome," but finding no federal-state conflict for the presumption to overcome); *see also Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000) (deferring on question whether presumption against preemption applies in context of implied conflict preemption). This Court has, by contrast, applied a presumption against preemption in cases involving express preemption, *e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517-18 (1992), or field preemption, *e.g.*, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). However, even in cases involving statutory construction, the "presumption against preemption" has not been consistently applied and is not free from controversy. It has been ignored in many recent express preemption

(continued...)

Such a federal-state conflict arises when "compliance with both federal and state regulations is a physical impossibility," *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). *E.g.*, *de la Cuesta*, 458 U.S. at 153. "[B]oth forms of conflicting state law are 'nullified' by the Supremacy Clause, and [this Court] has assumed that Congress would not want either kind of conflict." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (internal citations omitted). Thus, once a federal-state conflict is established, preemption is "inescapable and requires no inquiry into congressional design." *Fla. Lime*, 373 U.S. at 142-43; *see also Geier*, 529 U.S. at 869 ("ordinary pre-emption principles . . . instruct us to read statutes as pre-empting state laws (including common-law rules) that 'actually conflict' with the statute or federal standards promulgated thereunder").

As both the D.C. Circuit and Eleventh Circuit have recognized, this Court's teaching cannot coexist with a presumption against preemption in implied conflict preemption cases. *See Irving v. Mazda Motor Co.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no

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[7](...continued)
cases, *e.g.*, *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002) (relying on "natural[] read[ing]" of express preemption clause without any mention of presumption), and squarely rejected as a guide to interpreting express preemption clauses by at least two Members of this Court, *e.g.*, *Cipollone*, 505 U.S. at 544 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part) ("Under the Supremacy Clause, . . . our job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly but in accordance with their apparent meaning."); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 457 (2005) (opinion of Thomas, J.) (same).

presumption exists against preemption."), *cert. denied*, 525 U.S. 1018 (1998); *Conference of State Bank Supervisors v. Conover*, 710 F.2d 878, 882 (D.C. Cir. 1983) ("the 'presumption [against preemption]' inquiry is not relevant here, for the only question before us is whether admittedly conflicting regulations are valid").[8]

Indeed, the Framers left no doubt that there can be no presumption against preemption of conflicting state law, and that federal law is supreme without need for a showing of a Congressional preemptive intent, by placing that statement of intent within the text of the Supremacy Clause. *See* U.S. Const., art. VI, cl. 2 ("[T]he laws of the United States . . . shall be the supreme Law of the Land . . . *any Thing in the*

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[8] A close review of this Court's recent preemption jurisprudence in cases involving state tort law claims demonstrates that it is the existence or non-existence of a conflict – rather than any presumption – that has informed the Court's rulings. *See Bates*, 544 U.S. 431 (2005) (no express preemption of state tort law claims alleging inefficacy of pesticide because EPA does not evaluate pesticide efficacy nor approve pesticide labeling in that regard, but holding that fraud and failure-to-warn claims might be preempted to the extent based on requirements inconsistent with EPA regulation); *Sprietsma*, 537 U.S. 51 (2002) (no implied preemption where federal coast guard had not taken position on whether propeller guards should be required on motor boats); *Buckman*, 531 U.S. 341 (2001) (fraud-on-the-FDA claims impliedly preempted in light of conflict with FDA regulatory authority); *Geier*, 529 U.S. 861 (2000) (state tort law claims for failure to install airbags impliedly preempted due to conflict with federal law despite savings clause in National Traffic and Motor Vehicle Act precluding finding of express preemption); *Lohr*, 518 U.S. 470 (1996) (rejecting express preemption of state tort law claims involving Section 510(k) medical device because the generality of FDA requirements in approving such devices did not provide basis for state-federal law conflict); *see also id.* at 504 (Breyer, J., in controlling concurrence, explaining that preemption would be necessary if conflict existed).

Constitution or Laws of any State to the Contrary notwithstanding.") (emphasis added). During the Constitutional Convention, the delegates specifically debated whether the source of federal law supremacy should be an affirmative assertion by Congress – *i.e.* some statement as might be needed to rebut a presumption against preemption – or the fundamental hierarchy between federal and state laws. They decided on the latter and charged the courts to declare conflicting state laws void without awaiting any statement of preemptive intent by Congress. *See id.*; *see also* The Federalist No. 78 (Alexander Hamilton) ("The interpretation of the laws is the proper and peculiar province of the courts. . . . [I]n regard to the interfering acts of a superior and subordinate authority, ... it will be the duty of the judicial tribunals to adhere to [the supreme law].").

The Framers' rejection of any presumption against conflict preemption is made evident by the history behind the drafting of the Supremacy Clause. Early in the Convention, Governor Edmund Randolph proposed fifteen resolutions, primarily drafted by James Madison, which became known as the Virginia Plan. The sixth resolution dealt generally with the affirmative powers of Congress – the functional equivalent under the Virginia Plan of the Constitution's Article I, Section 8. I The Records of the Federal Convention of 1787, at 21 (M. Farrand ed., rev. ed. 1937). Among the powers allocated to Congress under this resolution was the authority "to negative all laws passed by the several States, contravening in the opinion of the National Legislature the articles of Union." *See id.* In other words, under this proposal, Congress would be required to declare whether conflicting state law would be preempted.

In response to the Virginia Plan, William Patterson, proposed nine alternative resolutions which became known as

the New Jersey Plan or the Small State Plan. The sixth of Patterson's resolutions was in substance and concept, if not in form, similar to the current language of the Supremacy Clause. *See id.* at 245. Patterson's sixth resolution differed from Randolph's power to negative state laws in that the former was not proposed as one of Congress's affirmative powers. All such powers under the Small State Plan were proposed in Patterson's second resolution. *See id.* at 243. The supremacy concept was instead offered as a separate resolution, distinct from legislative powers and listed after the fifth resolution establishing the federal judiciary. *See id.* at 244. That is, the courts – not Congress – would determine whether there was a preemptive conflict between federal and state law.

Resolution of the competing proposals came when the Convention debated the report of the Committee of the whole House. As he had done throughout the debates, *see id.* at 169 (June 8, 1787), 317 (June 19, 1787), James Madison warned against the "propensity of the States to pursue their particular interests in opposition to the general interest" and advocated "the negative on the laws of the States as essential to the efficacy & security of the Genl. Govt," 2 The Records of the Federal Constitutional Convention of 1787, at 27 (M. Farrand ed., rev. ed. 1937). Roger Sherman responded, "Such a power involves a wrong principle, to wit, that a law of a State contrary to the articles of the Union, would if not negatived, be valid & operative." *Id.* Randolph's proposal for a legislative power to negative state laws was thereafter defeated by a vote of three to seven. *See id.*

The Convention then immediately adopted by unanimous consent an alternative proposal by Luther Martin which is in substance similar to Patterson's sixth resolution and in form almost identical to the current Supremacy Clause. *See id.* at 28-29. Consistent with the structure of Patterson's plan, the

adopted text that became the Supremacy Clause does not mention any affirmative authority of Congress to repeal state law, but rather made federal law supreme over conflicting state law in all instances. *See* U.S. Const., art. VI, cl. 2; *see also* The Federalist No. 78.

Conflict preemption cases thus represent the paradigmatic operation of the Supremacy Clause to resolve conflicts between state and federal law. In declining to find preemption "[u]ntil and unless Congress states explicitly that it intends invalidation of state common law claims," Pet. App. 24a, the Second Circuit below contravened the fundamental constitutional principles underlying implied conflict preemption and departed from this Court's unambiguous teaching. *See Geier*, 529 U.S. at 884-85 ("[C]onflict pre-emption . . . turns on the identification of 'actual conflict,' and not on an express statement of preemptive intent. . . . [T]he Court has never before required a specific, formal agency [or congressional] statement identifying conflict in order to conclude that such a conflict in fact exists."); *Int'l Paper Co. v. Ouellette*, 479 U.S. 481 (1987) ("[I]t is not necessary for a federal statute to provide explicitly that particular state laws are pre-empted."); *Brown*, 468 U.S. at 501 ("[e]ven in the absence of such express language or implied congressional intent to occupy the field, we may nevertheless find state law to be displaced to the extent that it actually conflicts with federal law"); *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) ("[W]hen Congress has chosen to legislate pursuant to its constitutional powers, then a court must find local law pre-empted by federal regulation whenever the 'challenged state statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."'") (citations omitted).

The Second Circuit's application of a presumption against preemption to avoid implied conflict preemption of Respondent's fraud-on-the-FDA claims was in error. No such presumption exists against implied conflict preemption.

CONCLUSION

The Second Circuit's rejection of this Court's holding in *Buckman* based on a misplaced "presumption against preemption" highlights the need for further guidance from this Court on the proper scope, if any, of such a presumption. For the reasons set forth herein, WLF respectfully requests that this Court make clear that no such presumption can be applied in cases involving drug manufacturer regulatory submissions in the approval and regulation of prescription drugs due to the long-standing significant federal presence in that area. WLF also requests that this Court confirm that no presumption against preemption exists in cases intruding upon a federal agency's primary jurisdiction or in cases of implied conflict preemption.

Respectfully submitted,

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